

EXHIBIT 1



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Title of Action: Bryant C. Dunaway vs. Purdue Pharma L.P.

Document(s) Type: Summons/Complaint

Nature of Action: Others

Court/Agency: Cumberland County Circuit Court, TN

Case/Reference No: CCI-2018-cv-6331

Jurisdiction Served: Tennessee

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April 1, 2019

RE: Dunaway, et al. v. Purdue Pharma

Please find attached this matter's operative protective order to be served onto your party along with the attached redacted complaint filed on even date herewith.

Please review and forward to your party with the complaint and a copy of this letter. As soon as your party agrees to be bound by its terms, we will be happy to forward your party's counsel an unredacted version of this Amended Complaint. In the spirit of expediting the process of distributing the unredacted Amended Complaint, Plaintiffs stipulate that your party's consent to the protective order does not waive any of your party's rights to present any defense pursuant to Rule 12.02 the Tennessee Rules of Civil Procedure.

Sincerely,



Tricia Herzfeld

TH/jas

IN THE CIRCUIT COURT FOR CUMBERLAND COUNTY
AT CROSSVILLE, TENNESSEE

BRYANT C. DUNAWAY, *etc., et al.*,

Plaintiffs,

v.

PURDUE PHARMA, L.P., *et al.*,

Defendants.

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No. CCI-2018-cv-6331

Judge Young

AGREED PROTECTIVE ORDER

The parties in this action anticipate that certain of their confidential records, as well as those of nonparties, may be produced in discovery in the above-captioned action (the “Action”) and that such records, to the extent confidential, may require protection from further disclosure. Pursuant to Tennessee Rule of Civil Procedure 26.03, the Court finds good cause for entry of this Agreed Protective Order (“Order”) to provide such protection according to the terms and conditions set forth below. To expedite the flow of discovery material and the litigation of this case, facilitate the prompt resolution of any disputes over confidentiality, and adequately protect confidential, it is, by agreement of the Parties, STIPULATED and ORDERED:

1. SCOPE:

(a) **Generally.** All materials produced or adduced in the course of discovery in this Action, including initial or amended disclosures, responses to interrogatories and requests for admission, responses to discovery requests, deposition testimony and exhibits, documents, and testimony, data, and other information produced or disclosed (“Discovery Material”), shall be subject to this Order concerning Confidential or Highly Confidential – Attorneys’ Eyes Only

Information as defined below. This Order is subject to the Local Rules of this Court and the Tennessee Rules of Civil Procedure on matters of procedure and calculation of time periods.

(b) **Party Definitions.** A Party (or, if applicable, non-party) producing information covered by this Order shall be referred to as the “Designating Party.” Any Party (or, if applicable, non-party) receiving Discovery Material covered by this Order shall be referred to as the “Receiving Party.”

(c) **Derivative Material, Compilations.** The protections conferred by this Order cover Discovery Material designated as Confidential or Highly Confidential – Attorneys’ Eyes Only and also: (1) any information copied or extracted from such Discovery Material; and (2) all copies, excerpts, summaries, or compilations of such Discovery Material.

(d) **Materials Not Covered.** The protections conferred by this Order do not cover any information that has been published or that is not Discovery Material as defined in Paragraph 1(a) of this Order, unless the information was subject to confidentiality obligations when obtained, or was obtained or shared improperly.

(e) **Designations by a Non-Party.** Any non-party to this Action may designate any Discovery Material it produces as Confidential or Highly Confidential – Attorneys’ Eyes Only pursuant to the terms of this Order, and in so designating the non-party and the Parties agree that the restrictions and terms of this Order shall be applicable to all such Discovery Material to the same extent as Discovery Material produced by a Party. The non-party producing Discovery Material must first complete the certification contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound.

2. **CONFIDENTIAL INFORMATION:**

As used in this Order, “Confidential” Information means information designated as “Confidential” by the Designating Party that falls within one or more of the following categories: (1) information prohibited from disclosure by any applicable laws and regulations, including the Health Insurance Portability Accountability Act of 1996; (2) information that reveals trade secrets; (3) confidential research, development, or commercial information, *see* Tenn. R. Civ. P. 26.03; (4) medical information concerning any individual; (5) personal identity information; (6) income tax returns (including attached schedules and forms), W-2 forms and 1099 forms; or (7) personnel or employment records. Information or documents that are available to the public may not be designated as Confidential Information.

3. **HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY INFORMATION:**

As used in this Order, “Highly Confidential – Attorneys’ Eyes Only Information” means information designated as “Highly Confidential – Attorneys’ Eyes Only” by the Designating Party that the Designating Party in good faith believes could reasonably result in commercial, financial, or business injury to the Designating Party (other than injury to the Designating Party’s position in this Action) in the event of the disclosure, dissemination, or use by or to any of the persons not enumerated in Paragraph 6(c).

(a) **Designation.** The Designating Party may designate a document or other Discovery Material at the time of production as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information for protection under this Order by placing or affixing the words “Confidential” or “Highly Confidential – Attorneys’ Eyes Only” on each page of the document or material to be designated and on all copies in a manner that will not interfere with the legibility of the document or material. The designation of Discovery Material as Confidential Information or

Highly Confidential – Attorneys’ Eyes Only Information is a certification by an attorney or a party appearing *pro se* that the Discovery Material contains Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information as defined in this Order.

(b) As used in this Order, “copies” includes electronic images, duplicates, extracts, summaries, or descriptions that contain the Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information. Electronic media (such as CDs and DVDs) shall, at the time of production, be designated by affixing a label to such media. In the case of initial or amended disclosures, interrogatory answers, responses to requests for admissions, and other similar documents providing information, the designation shall be made by means of a statement in the relevant document specifying that the document or specific parts thereof are designated Confidential or Highly Confidential – Attorneys’ Eyes Only.

(c) Any copies that are made of any documents marked Confidential or Highly Confidential – Attorneys’ Eyes Only shall also be so marked. Indices, electronic databases, or lists of documents that do not contain substantial portions or images of the text of marked documents and do not otherwise disclose the substance of the Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information are not required to be marked.

4. **DEPOSITIONS:**

Deposition testimony is protected by this Order only if designated as Confidential or Highly Confidential – Attorneys’ Eyes Only on the record at the time the testimony is taken or by serving a Notice of Designation on all parties of record identifying the specific portions of the transcript that are designated Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information within thirty days after the Designating Party receives a certified copy of the deposition transcript from the court reporter. All deposition transcripts shall be treated as Highly

Confidential – Attorneys’ Eyes Only Information until the expiration of the thirty day period to make a written confidentiality designation. The failure to serve a timely Notice of Designation waives any designation of deposition testimony as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information, except for that testimony that was so designated on the record at the time of the testimony, unless otherwise ordered by the Court. Where confidentiality designations of deposition testimony are made orally on the record during a deposition, the Designating Party shall confirm that designation in a writing within thirty days after receiving the certified transcript.

5. NON-DOCUMENTARY AND NON-TESTIMONIAL MATERIAL:

Statements made in open Court shall not presumptively be deemed Confidential. Non-documentary and non-testimonial material, such as oral statements, shall be designated as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information if and as appropriate at the time of disclosure or in writing within thirty days of their disclosure or as otherwise ordered by the Court.

6. PROTECTION OF CONFIDENTIAL MATERIAL:

(a) **General Protections.** Confidential Information and Highly Confidential – Attorneys’ Eyes Only Information shall not be used or disclosed by the Parties, counsel for the Parties, or any other persons identified in subparagraphs (b) and (c) for any purpose whatsoever other than in this Action and any appeal thereto, except as the Designating Party may otherwise agree in writing.

(b) **Limited Third-Party Disclosures of Confidential Information.** The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Confidential Information to any person or entity except as set forth in subparagraphs (1)-(10).

Subject to these requirements, the following categories of persons may be allowed to review Confidential Information:

(1) **Counsel.** Counsel for the Parties and employees of counsel who have responsibility for the Action, unless doing so could render any Confidential Information subject to public disclosure;

(2) **Parties.** Individual Parties and present or former officers, directors, and employees of a Party (provided that no former employee shall be shown documents prepared after the date of his or her departure) but only to the extent counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Action and provided that such persons are not subject to laws requiring the production of the Confidential Information as part of any public records requests, and further provided that such persons have completed the certification contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound;

(3) **The Court and its Personnel;**

(4) **Court Reporters and Recordors.** Court reporters, recorders, and other personnel engaged for transcribing or videotaping testimony in this Action ("Court Reporters and Recordors");

(5) **Contractors.** Those persons specifically engaged for the limited purpose of making copies of Discovery Material or organizing or processing Discovery Material, including outside vendors hired to process electronically stored documents, copying services, litigation support services, translation services, graphics and design services, and document review and handling services, as well as investigators, trial consultants, jury consultants, and mock jurors, but only after such persons have completed the certification

contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound ("Contractors");

(6) **Experts.** Retained experts and expert consultants employed by the parties or counsel for the parties to assist in the preparation and trial of this action subject to the provisions of Paragraphs 7-8 below but only after such persons have completed the certification contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound ("Experts");

(7) **Witnesses at Depositions.** In connection with their depositions, witnesses in this Action to whom disclosure is reasonably necessary, but only: (1) if the Designating Party is notified of the intent to use Confidential Information no less than five days in advance of the scheduled deposition; and (2) after such persons have completed the certification contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound. Witnesses shall not retain a copy of documents containing Confidential Information, except witnesses may receive a copy of all exhibits marked at their depositions solely in connection with review of the transcripts and must return all copies after their review. Pages of transcribed deposition testimony or exhibits to depositions that are designated as Confidential Information pursuant to the process set out in this Order may not be disclosed to anyone except as permitted under this Order. In no event will a current or prior officer, director, employee, or affiliate of one defendant be shown the Confidential Discovery Material of another defendant unless the witness authored, sent, modified, or received the Discovery Material in the ordinary course of business;

(8) *Author, Sender, or Recipient.* Any non-party witnesses to the extent that the person authored, modified, sent, or received the Discovery Material prior to its production in this Action in the ordinary course of business, provided that the non-party witnesses shall only be shown the specific portions of the Discovery Material authored, sent, or received by the witness, that counsel for the Receiving Party determines in good faith that the employee's assistance is reasonably necessary to the conduct of this Action, and that such persons have completed the certification contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound;

(9) *Special Masters.* Special masters, mediators, arbitrators, or other third parties appointed by the Court or jointly retained by the Parties for settlement purposes or resolution of discovery or other disputes in this Action and their necessary staff, but only after such persons have completed the certification contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound ("Special Masters"); and

(10) *Others by Consent or Court Order.* Other persons only by written consent of the Designating Party or upon order of the Court and on such conditions as may be agreed or ordered.

(c) **Limited Third-Party Disclosures of Highly Confidential – Attorneys' Eyes Only Information.** The Receiving Party and counsel for the Receiving Party shall not disclose or permit the disclosure of any Highly Confidential – Attorneys' Eyes Only Information to any person or entity except as set forth in subparagraphs (1)-(6). Subject to these requirements, only the following categories of persons may be allowed to review Highly Confidential – Attorneys' Eyes Only Information:

(1) *Counsel.* Plaintiffs' counsel who have responsibility for this Action, unless doing so could render any Highly Confidential – Attorneys' Eyes Only Information subject to public disclosure; Defendants' outside counsel who have responsibility for this Action; and employees of Parties' counsel who have responsibility for this Action;

(2) *The Court and its Personnel, Court Reporters and Recorders; Contractors, Experts, and Special Masters;*

(3) *Witnesses at Depositions.* In connection with their depositions, witnesses in this Action to whom disclosure is reasonably necessary, but only when the witness authored, sent, modified, or received the Discovery Material in the ordinary course of business and provided that the witness shall only be shown the specific portions of the Discovery Material to which access is reasonably necessary, with all other designated material redacted, but only after such persons have completed the certification contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound. Witnesses shall not retain a copy of documents containing Highly Confidential – Attorneys' Eyes Only Information, except witnesses may receive a copy of all exhibits marked at their depositions solely in connection with review of the transcripts, and must return all copies after their review. Pages of transcribed deposition testimony or exhibits to depositions that are properly designated as Highly Confidential – Attorneys' Eyes Only Information pursuant to the process set out in this Order and may not be disclosed to anyone except as permitted under this Order. In no event will a current or prior officer, director, or employee, or affiliate of one defendant be shown the Highly Confidential – Attorney's Eyes Only Discovery Material of another defendant unless the witness authored, sent, modified or received the Discovery Material in the ordinary course of business;

(4) ***Author, Sender, or Recipient.*** Any witness, to the extent that it is evident that the person authored, sent or received the Discovery Material prior to its production in this Action in the ordinary course of business, provided that the witnesses shall only be shown the specific portions of the Discovery Material authored, sent, or received by the witness, with all other designated material redacted, and has completed the certification contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound;

(5) ***Others by Consent.*** Other persons only by written consent of the Designating Party or upon order of the Court and on such conditions as may be agreed or ordered; and

(6) ***Experts.*** Retained experts and expert consultants employed by the parties or counsel for the parties to assist in the preparation and trial of this action, subject to the provisions of Paragraphs 7-8 below but only after such persons have completed the certification contained in Attachment A, Acknowledgement of Understanding and Agreement to Be Bound.

(d) **Control of Documents.** Counsel for the Parties shall make reasonable efforts to prevent unauthorized or inadvertent disclosure of Confidential Information and Highly Confidential – Attorneys’ Eyes Only Information. Counsel to the Party employing, examining, or interviewing witnesses shall be responsible for obtaining the executed Acknowledgment of Understanding and Agreement to Be Bound, shall maintain the originals of that form for a period of three years after the termination of the case, and shall serve it on counsel upon request.

7. DISCLOSURE TO EXPERTS AND EXPERT CONSULTANTS:

Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information may be provided to retained experts and expert consultants assisting counsel to the Parties in this Action only to the extent necessary for the expert or expert consultant to prepare a written opinion, to prepare to testify, or to assist counsel in the prosecution or defense of this Action and provided that the expert or expert consultant is using said Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information solely in connection with the rendition of expert services in this Action and is not currently a partner, director, officer, employee, or other affiliate of the Designating Party.

8. LIMITATIONS:

Entering into, agreeing to, producing, or receiving Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information pursuant to this Order, or the taking of any action pursuant to this Order shall not:

(a) Limit or restrict a Party’s handling and use of its own Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information that has been designated as such solely by that Party;

(b) Prejudice in any way the rights of any Party to petition the Court to seek additional protection for Discovery Material for any reasons not specifically addressed by this Order;

(c) Prejudice in any way the rights of any Party to object to the relevancy, authenticity, or admissibility into evidence of any document or other information subject to this Order, or otherwise constitute or operate as an admission by any Party that any particular document or other information is or is not relevant, authentic, or admissible into evidence at any deposition, at trial, or in a hearing; or

(d) Prevent the interested Parties from agreeing, in writing, to alter or waive the provisions or protections of this Order with respect to any particular document, information, or person.

9. **INADVERTENT FAILURE TO DESIGNATE AND MIS-DESIGNATION:**

An inadvertent failure to designate Discovery Material as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information or mis-designation of Discovery Material does not, standing alone, waive the right to designate or re-designate the Discovery Material or constitute a waiver of a claim of confidentiality. A failure to designate or correctly designate Discovery Material may be corrected by prompt written notice upon discovery of such failure, accompanied by appropriately designated substitute copies of the Discovery Material. No Party shall be found to have violated this Order for failing to maintain the confidentiality of material during a time when that material has not been designated as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information, even where the failure to so designate was inadvertent and where the material is subsequently designated as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information. If a party designates or re-designates Discovery Material as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information after it was initially produced, the Receiving Party, on notification of the designation and receipt of substitute copies, must make a reasonable effort to promptly destroy or return to the Designating Party all copies of such non-designated or mis-designated Discovery Material and shall treat the substitute Discovery Material as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information as appropriate as if it had been initially so designated. If the Receiving Party disclosed Discovery Material that was subsequently designated as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information, it shall in good faith

assist the Designating Party in retrieving such Discovery Material from all recipients not entitled to access to such Discovery Material and prevent further disclosures except as authorized under the terms of this Order.

10. INADVERTENT PRODUCTION OF PRIVILEGED INFORMATION:

(a) **Generally.** Any inadvertent disclosure of Discovery Material subject to a claim of attorney client privilege, attorney work product protection, common-interest privilege, or any other privilege, immunity or protection from production or disclosure (“Privileged Information”) will not in any way prejudice or otherwise constitute a waiver of, or estoppel as to, such Privileged Information or generally of such privilege.

(b) Given the complexities associated with large-scale discovery, production of Privileged Information shall be deemed inadvertent whenever the Designating Party asserts in writing that such production was inadvertent.

(c) **Notice of Inadvertent Production.** If a Party or non-party discovers that it has inadvertently produced Privileged Information, it shall promptly notify the Receiving Party of the inadvertent production in writing, shall identify the inadvertently produced Privileged Information by Bates range where possible, and may demand that the Receiving Party return or destroy the Privileged Information. In the event that a Receiving Party receives information that it believes is subject to a good faith claim of privilege by the Disclosing Party, the Receiving Party shall immediately refrain from examining the information and shall promptly notify the Disclosing Party in writing that the Receiving Party possesses potentially Privileged Information. The Disclosing Party shall have fourteen (14) days to assert privilege over the identified information. If the Disclosing Party does not assert a claim of privilege in writing within the fourteen day period, the information in question shall be deemed non-privileged.

(d) **Claw Back of Privileged Information.** If the Designating Party has notified the Receiving Party of inadvertent production, or has confirmed the inadvertent production called to its attention by the Receiving Party, the Receiving Party shall within fourteen (14) days of receiving such written notification or confirmation: (1) destroy or return to the Designating Party all copies or versions of the inadvertently produced Privileged Information requested to be destroyed returned or destroyed; (2) delete from its work product or other materials any quoted or paraphrased portions of the inadvertently produced Privileged Information; and (3) ensure that inadvertently produced Privileged Information is not disclosed in any manner to any Party or non-party. Notwithstanding the above, the Receiving Party may segregate and retain one copy of the clawed back information solely for the purpose of disputing the claim of privilege. The Receiving Party shall not use any inadvertently produced Privileged Information in connection with this Action or for any other purpose other than to dispute the claim of privilege. The Receiving Party may file a motion disputing the claim of privilege and seeking an order compelling production of the material at issue; the Disclosing Party may oppose any such motion, including on the grounds that inadvertent disclosure does not waive privilege. If the Receiving Party disclosed Discovery Material that was subsequently designated as Privileged Information, it shall in good faith assist the Designating Party in retrieving such Discovery Material from all recipients not entitled to access to such Discovery Material and prevent further disclosures except as authorized under the terms of this Order.

11. **UNAUTHORIZED DISCLOSURE:**

If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information to any person or in any circumstance not authorized under this Order, the Receiving Party must immediately: (1) notify

the Designating Party in writing of the unauthorized disclosures; (2) use its best efforts to retrieve all copies of the Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information; (3) inform the person or persons to whom unauthorized disclosures were made of this Order, and (4) request such person or persons complete the certification contained in Attachment A, Acknowledgment of Understanding and Agreement to Be Bound.

12. FILING OF CONFIDENTIAL OR HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY DISCOVERY MATERIAL:

Any party wishing to file a document designated as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information in connection with a motion, brief, or other submission to the Court, or file a motion, brief, or other submission containing Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information, must file said submission under seal unless otherwise agreed by the Parties.

13. DISPUTES CONCERNING CONFIDENTIALITY DESIGNATIONS:

The following procedure shall apply to disputes concerning the designation of material as Confidential or Highly Confidential – Attorney Eyes Only:

(a) **Meet and Confer.** A Party who disputes the designation of Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information must do so in good faith and must begin the process by conferring directly with counsel for the Designating Party either in person or through correspondence. In conferring, the Receiving Party must explain the basis for its belief that the confidentiality designation was not proper and must give the Designating Party an opportunity to review the designated material, to reconsider the designation, and, if no change in designation is offered, to explain the basis for the designation. If the Receiving Party believes that portion(s) of a document are not Confidential or Highly Confidential – Attorneys’ Only Information, it will identify the information that it believes is not confidential and the Designating

Party will review and respond, as laid out in this paragraph, with respect to that specific information. The Designating Party may respond regarding the disputed material within seven days of the meet and confer.

(b) **Removing Confidential Designation.** A party's failure to reject a Confidentiality designation shall in no way prejudice its right to subsequently, during the course of this litigation, seek to remove the Confidentiality designation assigned to any materials. The Party seeking to remove the Confidentiality designation shall file an appropriate motion with this Court detailing why the materials should not be protected from disclosure. Each such motion must be accompanied by a competent declaration that affirms that the movant has complied with the meet and confer requirements of this procedure. The burden of persuasion in any such challenge proceeding shall be on the Designating Party. Until the Court rules on the challenge, all parties shall continue to treat the materials as Confidential Information or Highly Confidential – Attorneys' Eyes Only Information, as appropriate, under the terms of this Order.

(c) **Action by the Court.** Applications to the Court for an order relating to materials or documents designated Confidential Information or Highly Confidential – Attorneys' Eyes Only Information shall be by motion. Nothing in this Order or any action or agreement of a Party under this Order limits the Court's power to make orders concerning the disclosure of documents produced in discovery or at trial.

14. USE OF CONFIDENTIAL INFORMATION OR HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY INFORMATION AT HEARINGS (INCLUDING TRIAL):

There shall be no presumption of confidentiality at trial, and absent agreement or Court order, materials that are designated Confidential or Highly Confidential – Attorneys' Eyes Only will not be precluded from use at trial because of such designation. Except for filings that have already been submitted to the Court, a Party that intends to present to the Court Confidential

Information or Highly Confidential – Attorneys’ Eyes Only Information at a hearing shall bring that to the Parties’ attention prior to the hearing to allow a party the opportunity to request appropriate measures from the Court to prevent disclosure. The Court may thereafter make such orders, including any stipulated orders, as are necessary to govern the use of Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information at the hearing.

15. CONFIDENTIAL INFORMATION OR HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY INFORMATION REQUESTED BY THIRD PARTY; PROCEDURE FOLLOWING REQUEST:

(a) If any person receiving Discovery Material covered by this Order (the “Receiver”) is served with a subpoena, a request for information (including under any Public Disclosure Laws as defined below), or any other form of legal process that would compel disclosure of any Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information that was produced by a person or entity other than the Receiver (“Request”), the Receiver must so notify the Designating Party, in writing, within ten days after receiving the Request. Such notification must include a copy of the Request.

(b) The Receiver also must, prior to disclosure, inform the party who made the Request (“Requesting Party”) in writing that some or all the requested material is the subject of this Order. In addition, the Receiver must deliver a copy of this Order promptly to the Requesting Party.

(c) The purpose of imposing these duties is to alert the interested persons to the existence of this Order and to afford the Designating Party in this case an opportunity to try to protect its Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information. The Designating Party shall bear the burden and the expense of seeking protection of its Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information, and nothing in these provisions should be construed as authorizing or encouraging the Receiver in this Action to disobey a lawful directive from a court. The obligations set forth in this paragraph remain in

effect while the Receiver has in its possession, custody, or control Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information by the other Party in this Action.

(d) Materials that have been designated as Confidential or Highly Confidential-Attorneys’ Eyes Only Discovery Material shall not be provided or disclosed to any third party in response to a request under the Tennessee Public Records Act, Tenn. Code Ann. § 10-7-501 *et seq.*, or any similar federal, state, or municipal law (collectively, the “Public Disclosure Laws”) unless this Court, at the request of any Party or any third party or on this Court’s own motion, shall approve said disclosure. The provisions of this section shall apply to any person or entity in receipt of Confidential or Highly Confidential-Attorneys’ Eyes Only Discovery Material governed by this Order. Nothing in this Order shall be deemed to: (1) foreclose any party from arguing that Discovery Material is not a public record for purposes of the Public Disclosures Law; (2) prevent any party from claiming any applicable exemption to the Public Disclosure Laws; or (3) limit any arguments that a party may make as to why Discovery Material is exempt from disclosure.

16. INFORMATION SUBJECT TO EXISTING OBLIGATION OF CONFIDENTIALITY:

In the event that a Party is required by a valid discovery request to produce any information held by it subject to an obligation of confidentiality in favor of a third party, the Party shall, promptly upon recognizing that such third party’s rights are implicated, provide the third party with a copy of this Order and inform the third party in writing: (1) of the Party’s obligation to produce such information in connection with this Action and of its intention to do so, subject to the protections of this Order; (2) of the third party’s right within twenty-one days to seek further protection or other relief from the Court if, in good faith, it believes such information to be confidential under the said obligation and either objects to the Party’s production of such information or regards the provisions of this Order to be inadequate; and (3) seek the third party’s

consent to such disclosure if it does not plan to object. Thereafter, the Party shall refrain from producing such information for a period of twenty-one days in order to permit the third party an opportunity to seek relief from the Court, unless the third party earlier consents to disclosure. If the third party fails to seek such relief, the Party shall promptly produce the information in question subject to the protections of this Order, or alternatively, shall promptly seek to be relieved of this obligation or for clarification of this obligation by the Court.

17. OBLIGATIONS ON CONCLUSION OF LITIGATION:

(a) **Order Continues in Force.** Unless otherwise agreed or ordered, this Order shall remain in force after dismissal or entry of final judgment not subject to further appeal.

(b) **Obligations at Conclusion of Litigation.** Within sixty-three days after dismissal or entry of final judgment not subject to further appeal, all Confidential Information and Highly Confidential – Attorneys’ Eyes Only Information under this Order, including copies as defined in Paragraph 4(a) above, shall be returned to the producing party unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the Parties agree to destruction to the extent practicable in lieu of return; or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that Party elects to destroy the documents and certifies to the producing party that it has done so.

(c) **Retention of Work Product and one set of Discovery Material.** Notwithstanding the above requirements to return or destroy documents, Plaintiffs’ outside counsel and Defendants’ outside counsel may retain: (1) attorney work product, including an index that refers or relates to designated Confidential or Highly Confidential – Attorneys’ Eyes Only Discovery Material so long as that work product does not duplicate verbatim substantial portions of Confidential Information; and (2) one complete set of all documents filed with the Court including those filed

under seal, deposition and trial transcripts, and deposition and trial exhibits. Any retained Confidential or Highly Confidential – Attorneys’ Eyes Only Discovery Material shall continue to be protected under this Order. An attorney may use his or her work product in subsequent litigation, provided that its use does not disclose or use Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information.

18. ORDER SUBJECT TO MODIFICATION:

This Order shall be subject to modification by the Court on its own initiative or on motion of a party or any other person with standing concerning the subject matter.

19. NO PRIOR JUDICIAL DETERMINATION:

This Order is entered based on the representations and agreements of the Parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any Discovery Material designated as Confidential or Highly Confidential – Attorneys’ Eyes Only is entitled to protection under Rule 26.03 of the Tennessee Rules of Civil Procedure or otherwise until such time as the Court may rule on a specific document or issue.

20. ADVICE TO CLIENTS:

This Order shall not bar any attorney in the course of rendering advice to such attorney’s client with respect to this Action from conveying to any party-client the attorney’s evaluation in a general way of Confidential Information produced or exchanged under the terms of this order; provided, however, that in rendering such advice and otherwise communicating with the client, the attorney shall not disclose the specific contents of any Confidential Information produced by another party if such disclosure would circumvent the purpose of or be contrary to the terms of this Order.

21. PERSONS BOUND:

This Order shall take effect when entered and shall be binding upon all counsel of record and their law firms, the parties, and persons made subject to this Order by its terms.

IT IS SO ORDERED.

*Entered pursuant to Rule 58 of the Tennessee
Rules of Civil Procedure*

JUDGE JONATHAN L. YOUNG

AGREED TO AND APPROVED FOR ENTRY:

<u>Attorneys for Endo Defendants:</u>	<u>Attorneys for Defendant Mallinckrodt:</u>
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CERTIFICATE OF SERVICE

I hereby certify that on November 15, 2018 a true and correct copy of the foregoing has been sent via e-mail and/or U.S. Mail to the following:

<u>Attorneys for Defendants Murphy and North Alabama Pain Services LLC:</u> BONE MCCALLESTER NORTON PLLC Edward M. Yarbrough (BPR # 4097) W. Justin Adams (BPR # 22433) 511 Union Street, Suite 1600 Nashville, TN 37219 (615) 238-6300 eyarbrough@bonelaw.com wjadams@bonelaw.com	<u>Attorneys for Defendant Montclair Health & Wellness, LLC:</u> Daniel J. Lewis 1337 Antioch Pike Nashville, TN 37211 (615) 422-8304 danielmurphy@danmurph.com
<u>Defendant Florence:</u> David Florence 185 Big Falls Circle Manchester, TN 37355	<u>Defendant Haskins:</u> Nathan Paul Haskins 20 Jones Circle Old Hickory, TN 37183



Attorney

**IN THE CIRCUIT COURT FOR CUMBERLAND COUNTY
AT CROSSVILLE, TENNESSEE**

Judge Young

The undersigned hereby acknowledges that he/she has read the Agreed Protective Order entered in the above-captioned action, and attached hereto, understands the terms. The undersigned submits to the jurisdiction of the Circuit Court for Cumberland County at Crossville, Tennessee in matters relating to the Agreed Protective Order and understands that the terms of the Agreed Protective Order obligate him/her to use materials designated as Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information in accordance with the Order solely for the purposes of the above-captioned action, and not to disclose any such Confidential Information or Highly Confidential – Attorneys’ Eyes Only Information to any other person, firm or concern.

The undersigned acknowledges that violation of the Agreed Protective Order may result in penalties of contempt of court.

Name: _____

Job Title: _____

Employer: _____

Business Address: _____

Date: _____

Signature: _____

CUMBERLAND County <div style="font-size: 48pt; font-weight: bold; opacity: 0.5; transform: rotate(-15deg); position: absolute; top: 50px; left: 50px;">COPY</div>	STATE OF TENNESSEE CIVIL SUMMONS page 1 of 1	Case Number CCI-2018-CV-6331 <div style="font-size: 24pt; font-weight: bold; position: absolute; bottom: 10px; right: 10px;">16347</div>
BRYANT C. DUNAWAY, ET AL. Vs. PURDUE PHARMA, L.P., ET AL.		

Served On:

**MCKESSON
CORPORATION**

Serve Via Its Registered Agent:

Corporation Service Company, 2908 Poston Avenue, Nashville, TN 37203

You are hereby summoned to defend a civil action filed against you in CIRCUIT Court CUMBERLAND County, Tennessee. Your defense must be made within thirty (30) days from the date this summons is served upon you. You are directed to file your defense with the clerk of the court and send a copy to the plaintiff's attorney at the address listed below. If you fail to defend this action by the below date, judgment by default may be rendered against you for the relief sought in the complaint.

Issued: April 1, 2019

Jessica Burgess / Morgan Burgess
 Clerk / Deputy Clerk

Attorney for Plaintiff: J. Gerard Stranch, IV, James G. Stranch, III, Tricia Herzfeld, Benjamin A. Gastel, Anthony A. Orlandi
Branstetter, Stranch & Jennings, PLLC, 223 Rosa L. Parks Ave., Ste. 200, Nashville, TN 37201, 615-254-8801

NOTICE OF PERSONAL PROPERTY EXEMPTION

TO THE DEFENDANT(S): Tennessee law provides a ten thousand dollar (\$10,000) personal property exemption as well as a homestead exemption from execution or seizure to satisfy a judgment. The amount of the homestead exemption depends upon your age and the other factors which are listed in TCA § 26-2-301. If a judgment should be entered against you in this action and you wish to claim property as exempt, you must file a written list, under oath, of the items you wish to claim as exempt with the clerk of the court. The list may be filed at any time and may be changed by you thereafter as necessary; however, unless it is filed before the judgment becomes final, it will not be effective as to any execution or garnishment issued prior to the filing of the list. Certain items are automatically exempt by law and do not need to be listed; these include items of necessary wearing apparel (clothing) for your self and your family and trunks or other receptacles necessary to contain such apparel, family portraits, the family Bible, and school books. Should any of these items be seized you would have the right to recover them. If you do not understand your exemption right or how to exercise it, you may wish to seek the counsel of a lawyer. Please state file number on list.

Mail list to _____, _____ Clerk, _____ County

CERTIFICATION (IF APPLICABLE)

I, Jessica Burgess, Circuit Clerk of Cumberland County do certify this to be a true and correct copy of the original summons issued in this case.

Date: April 1, 2019
Jessica Burgess / Morgan Burgess
 Clerk / Deputy Clerk

OFFICER'S RETURN: Please execute this summons and make your return within ninety (90) days of issuance as provided by law.

I certify that I have served this summons together with the complaint as follows: _____

Date: _____ By: _____

Please Print: Officer, Title

Agency Address

Signature

RETURN ON SERVICE OF SUMMONS BY MAIL: I hereby certify and return that on _____, I sent postage prepaid, by registered return receipt mail or certified return receipt mail, a certified copy of the summons and a copy of the complaint in the above styled case, to the defendant _____. On _____ I received the return receipt, which had been signed by _____ on _____. The return receipt is attached to this original summons to be filed by the Court Clerk.

Date: _____

Notary Public / Deputy Clerk (Comm. Expires _____)

Signature of Plaintiff

Plaintiff's Attorney (or Person Authorized to Serve Process)

(Attach return receipt on back)

**IN THE CIRCUIT COURT FOR CUMBERLAND COUNTY
AT CROSSVILLE, TENNESSEE**

**BRYANT C. DUNAWAY, in his official)
capacity as the District Attorney General for)
the Thirteenth Judicial District, TN and on)
behalf of all political subdivisions therein,)
including CLAY COUNTY, CITY OF CELINE)
CUMBERLAND COUNTY, CITY OF CRAB)
ORCHARD, CITY OF CROSSVILLE, TOWN)
OF PLEASANT HILL, DEKALB COUNTY,)
TOWN OF ALEXANDRIA, TOWN OF)
DOWELLTOWN, TOWN OF LIBERTY, CITY)
OF SMITHVILLE, OVERTON COUNTY,)
TOWN OF LIVINGSTON, PICKETT)
COUNTY, TOWN OF BYRDSTOWN,)
PUTNAM COUNTY, CITY OF ALGOOD,)
TOWN OF BAXTER, CITY OF)
COOKEVILLE, TOWN OF MONTEREY,)
WHITE COUNTY, TOWN OF DOYLE, CITY)
OF SPARTA;**

**) JURY DEMAND 6347
) Case No. CCI-2018-CV-6331**

**JENNINGS H. JONES, in his official capacity)
as the District Attorney General for the)
Sixteenth Judicial District, TN and on behalf of)
all political subdivisions therein, including)
CANNON COUNTY, TOWN OF)
AUBURNTOWN, TOWN OF WOODBURY,)
RUTHERFORD COUNTY, CITY OF)
EAGLEVILLE, CITY OF LA VERGNE, CITY)
OF MURFREESBORO, TOWN OF SMYRNA;)**

**ROBERT J. CARTER, in his official capacity)
as the District Attorney General for the)
Seventeenth Judicial District, TN and on behalf)
of all political subdivisions therein, including)
BEDFORD COUNTY, TOWN OF BELL)
BUCKLE, TOWN OF NORMANDY, CITY OF)
SHELBYVILLE, TOWN OF WARTRACE,)
LINCOLN COUNTY, CITY OF ARDMORE,)
CITY OF FAYETTEVILLE, TOWN OF)
PETERSBURG, MARSHALL COUNTY,)
TOWN OF CHAPEL HILL, TOWN OF)
CORNERSVILLE, CITY OF LEWISBURG,)
MOORE COUNTY, CITY OF LYNCHBURG;)**

BRENT A. COOPER, in his official capacity as)
the District Attorney General for)
the Twenty-Second Judicial District, TN and on)
behalf of all political subdivisions therein,)
including GILES COUNTY, CITY OF)
ELKTON, TOWN OF LYNNVILLE, CITY OF)
MINOR HILL, CITY OF PULASKI,)
LAWRENCE COUNTY, TOWN OF)
ETHRIDGE, CITY OF IRON CITY, CITY OF)
LAWRENCEBURG, CITY OF LORETTO,)
CITY OF ST. JOSEPH, MAURY COUNTY,)
CITY OF COLUMBIA, CITY OF MOUNT)
PLEASANT, CITY OF SPRING HILL,)
WAYNE COUNTY, CITY OF CLIFTON,)
CITY OF COLLINWOOD, CITY OF)
WAYNESBORO;)

LISA S. ZAVOGIANNIS, in her official)
capacity as the District Attorney General for)
the Thirty-First Judicial District, TN and on)
behalf of all political subdivisions therein,)
including VAN BUREN COUNTY, TOWN OF)
SPENCER, WARREN COUNTY, TOWN OF)
CENTERTOWN, CITY OF MCMINNVILLE,)
TOWN OF MORRISON, TOWN OF VIOLA;)

and BABY DOE, by and through his Mother;)

Plaintiffs,)

v.)

PURDUE PHARMA L.P.;)
PURDUE PHARMA INC.;)
THE PURDUE FREDERICK COMPANY INC;))
RICHARD SACKLER;)
MALLINCKRODT LLC;)
ENDO HEALTH SOLUTIONS INC;)
ENDO PHARMACEUTICALS, INC;)
TEVA PHARMACEUTICALS USA, INC.;)
DAVID FLORENCE;)
MARK MURPHY;)
NATHAN PAUL HASKINS;)
CENTER FOR ADVANCED MEDICINE,)
LLC;)

LYNNVILLE FAMILY MEDICAL CLINIC,)
LLC;)
MONTCLAIR HEALTH & WELLNESS)
LLC D/B/A SPECIALTY ASSOCIATES;)
and NORTH ALABAMA PAIN SERVICES,)
LLC;)
AMERISOURCEBERGEN DRUG)
CORPORATION;)
CARDINAL HEALTH, INC.,)
CARDINAL HEALTH PHARMACY)
SERVICES, LLC, CARDINAL HEALTH)
SPECIALTY PHARMACY, LLC;)
MCKESSON CORPORATION,)
CVS PHARMACY, INC., CVS HEALTH)
CORPORATION, CAREMARKPCS)
HEALTH, L.L.C. d/b/a CVS CAREMARK,)
WALGREENS BOOTS ALLIANCE, INC.)
AND WALGREEN CO., AS SUCCESSOR IN)
INTEREST TO RITE AID CORPORATION,)
RITE AID HDQTRS CORPORATION, and)
RITE AID OF TENNESSE.)
Defendants.)

SECOND AMENDED COMPLAINT

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I. INTRODUCTION

1. This is an action brought by a baby born dependent on opioids and by the District Attorneys who prosecute crimes in their respective communities against drug producers, Purdue executive Richard Sackler, drug distributors, pill mill prescribers, and retailers under the Tennessee Drug Dealer Liability Act. This action seeks compensation for the damages inflicted by the opioid epidemic, and to halt the illegal flood of highly addictive and destructive drugs into these Tennessee communities.

2. The opioid epidemic poses an ongoing crisis in Tennessee, particularly in areas rife with “pill mills.” From 2012 to 2017 (the last year for which data has been reported), Tennessee set a new state record each year for the number of opioid overdose deaths, with 1,186 in 2016 and 1,268 in 2017.¹ According to IMS Health data, in 2015, there were also a staggering 7.8 million opioid painkiller prescriptions filled in the state – or 1.18 prescriptions for every man, woman, and child, placing Tennessee number 2 in the nation among all states for the number of opioid prescriptions per capita. This trend continued in 2016, when there were 7.6 million painkiller prescriptions written in Tennessee.² In 2015, Tennessee had 14 of the top 50 counties in the country for painkiller usage, including Clay County, Pickett County, and Dekalb County.³

3. Along with overdose deaths, the number and rate of neonatal abstinence syndrome (“NAS”) – a condition suffered by babies born to mothers addicted to opioids – has also increased dramatically in Tennessee. In 2017, there were 1,015 NAS births in Tennessee.⁴ Since the initial

¹ Tennessee Department of Health, Tennessee Drug Overdose Data Dashboard. Available at: <https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html>.

[hereinafter “Tennessee Drug Overdose Data Dashboard”]

² See Opioid Facts in Tennessee, <https://1pstnvro9pz4ageywbeh0819me-wpengine.netdna-ssl.com/wp-content/uploads/2018/09/Opioid-Facts-Fall-2018.pdf>

³ *Id.*

⁴ *Id.*

filing of this lawsuit on January 10, 2018, there have been another 900 NAS births in Tennessee.⁵

4. Plaintiff BABY DOE was born dependent on opioids. Like the tragedy that besets thousands of children born dependent on opioids every year, the first days of his life were spent in excruciating pain, while doctors attempted to wean him from his opioid dependency. The birth mother of Plaintiff BABY DOE fell victim to an epidemic that has ravaged Tennessee, causing immense suffering to those born addicted to opioids and costing tens of thousands of dollars to local governments forced to deal with the aftermath. The Tennessee community into which Plaintiff BABY DOE was born is plagued by the opioid epidemic, resulting in high rates of addiction, record numbers of overdose deaths, alarming rates of babies born opioid-dependent, and an illegal opioids market that continues to thrive despite the best efforts of law enforcement to combat it.

5. The opioid epidemic did not appear overnight. It is the consequence of unconscionable greed perpetrated by Defendants PURDUE PHARMA L.P., PURDUE PHARMA INC., AND THE PURDUE FREDERICK COMPANY INC. (collectively “Purdue”), ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS, INC. (collectively “Endo”), MALLINCKRODT LLC (“Mallinckrodt”), and TEVA PHARMACEUTICAL USA, INC. (“Teva”) (collectively, “Producer Defendants”), AMERISOURCEBERGEN DRUG CORPORATION (“AmerisourceBergen”), CARDINAL HEALTH, INC. (“Cardinal Health”), and MCKESSON CORPORATION (“McKesson”) (collectively, “Distributor Defendants”), CVS PHARMACY, INC., CVS HEALTH CORPORATION (“CVS”), CAREMARKPCS HEALTH, L.L.C. d/b/a CVS CAREMARK (“CAREMARK”) and WALGREENS BOOTS ALLIANCE, INC.

⁵ Tennessee Department of Health, NAS Summary Archive. Available at: <https://www.tn.gov/health/nas/nas-summary-archive.html>.

and WALGREEN CO., as successor in interest to, RITE-AID CORPORATION, RITE AID HDQTRS CORPORATION, and RITE AID OF TENNESSEE (collectively, the “Retailer Defendants”), and Richard Sackler, who fueled the rampant addiction to opioid drugs that still ravages the general population. Particularly egregious was (and remains) the opioid producers’ unbridled distribution in pursuit of profit. Despite knowing about widespread diversion and illegal distribution of opioids by such actors as Defendants CENTER FOR ADVANCED MEDICINE, LLC, LYNNVILLE FAMILY MEDICAL CLINIC LLC, MONTCLAIR HEALTH & WELLNESS LLC D/B/A SPECIALTY ASSOC. and NORTH ALABAMA PAIN SERVICES, LLC, DAVID FLORENCE, MARK MURPHY, and NATHAN PAUL HASKINS (“Pill Mill Prescriber Defendants”), the opioid producers, distributors, and retailers continued to flood Tennessee with their highly addictive prescription drugs, which both perpetuated their multi-billion-dollar drug empire and propelled opioid abuse to unprecedented levels. As described herein, the Producer Defendants, the Distributor Defendants, the Retailer Defendants, and Richard Sackler committed various acts that were intended to – and did – facilitate illegal diversion of their drugs.

6. BABY DOE is a victim of Defendants’ avarice. He was born dependent on opioids, diagnosed with NAS, and forced to endure a painful start to his life: crying excessively, arching his back, refusing to feed, and shaking. After more than a decade of unbridled distribution of prescription opioids by Defendants and other industry actors, his birth mother’s community was awash in pain-killers, fueling a dramatic increase in those exposed to and addicted to oxycodone, hydrocodone, Percocet, OxyContin, Roxicodone, Opana, and other opioids.

7. Indeed, Defendants spent years pushing their drugs by selling drugs to illegitimate pill mills, convincing suspicious doctors that prescription opioids’ addictive properties had been

overblown, continuing to aggressively market opioids, and/or filling suspicious prescriptions even when these Defendants knew that millions of Americans and hundreds of thousands of Tennesseans were abusing and misusing prescription opioids and had no legitimate medical need for which prescription opioids should be consumed. Defendants continue to knowingly participate in and profit from the illegal opioid drug market that they helped create and/or supply. Defendants knew that entire regions of the country were being devastated by addiction to prescription drugs that they distributed. They also recognized that prescribers were writing – and pharmacies filling – volumes of opioids that necessarily were both creating and supplying large volumes of drug addicts and pill seekers. Nevertheless, Defendants persisted with distributing mind-boggling volumes of opioids into these same abuse-riddled communities, peddling the same misinformation to overcome prescribers' legitimate objections, urging suspect prescribers and pharmacies that supplied the illegal market to flood the market with even more opioids, and/or otherwise taking various measures to ensure that the flow of prescription opioids to feed drug addicts and pill seekers proceeded without impediment.

8. Under Tennessee law, prescription opioids are “Schedule II” controlled substances because they inherently have a “high potential for abuse” and that “may lead to severe psychic or physical dependence.”⁶ For this reason, everyone who handles prescription opioids in Tennessee (from production to retail sales) must maintain appropriate safeguards against abuse and diversion, and must ensure that the drugs are only being distributed to serve legitimate medical purposes.⁷ If either or both of these preconditions is not satisfied, it is unlawful to distribute prescription opioids in Tennessee. Indeed, entities holding a Tennessee license can be criminally prosecuted for

⁶ T.C.A. § 39-17-407.

⁷ See, e.g., T.C.A. § 53-11-302 and -303; Rules of Tn Bd. of Pharmacy, Ch. 1140-02.01 *et seq.* and Ch. 1140-09.01 *et seq.*

violating their responsibilities in the distribution chain.⁸ The Producer Defendants, Distributor Defendants, and Retailer Defendants did not lawfully distribute prescription opioids into or within Tennessee. Instead, using their licenses as a cover, they unlawfully distributed drugs without maintaining necessary controls (rendering the distribution unlawful), knowingly distributed those drugs into channels that they knew were resulting in diversion, knowingly encouraged high-volume pill mill prescribers to prescribe opioids without a legitimate medical purpose to feed drug abusers, pill seekers, and drug dealers, knowingly supplied pharmacies serving pill mills, and/or knowingly dispensed prescriptions that were not made for a legitimate medical purpose. Plaintiffs therefore assert that all drugs distributed in this manner (without appropriate controls, etc.) were unlawful and that defendants therefore knowingly participated in the illegal drug market in this fashion. Defendants also exceeded their lawful authority by taking actions that the federal government found were unlawful, that were not authorized by the FDA, the DEA, and Tennessee law or Tennessee authorities, and/or that specifically contradicted guidance from the FDA, the DEA, and Tennessee law or Tennessee authorities.

9. The Producer Defendants also committed various other acts intended to facilitate diversion and illegal drug sales, from which they knowingly sought to profit. These acts include, *inter alia*: waging a public campaign of misinformation concerning opioids (including through “key opinion leaders” and front groups); encouraging prescribers to engage in prescription practices that the Producer Defendants knew and expected would drive up addiction rates; repeatedly calling on and targeting the highest volume prescribers to prescribe more opioids while knowing that those prescribers were or were likely operating pill mills (including high-volume prescribers in small, rural Tennessee communities who were prescribing at utterly unjustifiable

⁸ See T.C.A. § 53-11-401(1).

levels); convincing naïve doctors willing to write prescriptions for powerful opioids to pill seekers and prescription drug abusers who sell the prescriptions wholesale; devising marketing strategies to overcome prescribers' legitimate objections to prescribing opioids for long-term use and in higher doses; convincing prescribers whom defendants knew were likely engaging in unlawful conduct and feeding the illegal drug market to prescribe even more opioids; incentivizing sales representatives to do business both with pill mills and with pharmacies supplying pill mills through volume-based compensation (and financially rewarding those sales associates for doing so); adding high-volume prescribers and pharmacies as customers without any due diligence, knowing that there was a strong likelihood that these high-volume businesses were running or supplying pill mills; filling suspicious orders despite knowing or reasonably suspecting that the orders reflected diversion; filling suspicious orders without any investigation; filling suspicious orders even where they met the Producer Defendants' own criteria for orders reflecting potential diversion; filling orders that they had subjectively identified as suspicious before undertaking or completing an investigation; continuing to do business with prescribers and pharmacies that had a history of suspicious prescribing or ordering practices; implementing sham suspicious order monitoring programs that were structured to fail and to allow diversion to proceed unimpeded; continuing to target pill mill prescribers to prescribe more opioids and to target associated pharmacies that served them, even after being told by law enforcement that they were likely feeding the illegal drug market; supplying outlandish volumes of prescription opioids to rural Tennessee communities far exceeding any conceivable medical need; and over-supplying Tennessee with opioids while recognizing that doing so would create addicts and feed or expand the illegal drug market. Defendants' actions included encouraging higher volumes of prescriptions, supplying, and/or otherwise doing business with entities in Tennessee and the Counties patently

engaging in diversion, such as Defendants CENTER FOR ADVANCED MEDICINE, LLC, LYNNVILLE FAMILY MEDICAL CLINIC LLC, MONTCLAIR HEALTH & WELLNESS LLC D/B/A SPECIALTY ASSOC. and NORTH ALABAMA PAIN SERVICES, LLC.

10. The Drug Distributors similarly committed acts intended to facilitate the diversion of drugs into the illegal drug market in Tennessee. The Distributor Defendants are major distributors of controlled substances, who supply 95% of the market. Like the Producer Defendants, the Distributor Defendants were aware of (and helped cause) a growing epidemic from abuse, addiction, and diversion of the prescription opioids they supplied nationwide and in Tennessee. The Distributor Defendants were aware of the quantities and frequency with which those drugs were distributed in Tennessee and the Counties, and they knew with reasonable certainty which prescribers were operating pill mills (or otherwise over-prescribing) and which pharmacies were supplying them. Nevertheless, they chose to do business with pharmacies and dispensing physicians whom they knew or reasonably believed were feeding the illegal drug market. Furthermore, the Distributor Defendants recognized that they had a responsibility not to fill suspicious orders, because filling those orders would foster diversion into the illegal drug market. The Distributor Defendants knew what types of orders were indicative of diversion, such as frequent and large orders by pharmacies in rural communities with low population, orders by pharmacies that Defendants recognized were serving pill mill operators, sharp increases in order volume without justification, orders for tablets exceeding the number of people in a community, and orders by pharmacies that distributors knew were filling prescriptions from “patients” who traveled hundreds of miles to fill the prescriptions. Upon information and belief, despite recognizing orders that reflected diversion, the Distributor Defendants processed and filled them anyway.

11. Moreover, upon information and belief, the Distributor Defendants collaborated with the Drug Producers to get around whatever sham suspicious order monitoring systems the Drug Producers may have put in place. When a Drug Producer asked about orders that were flagrantly suspicious and indicative of diversion, the Distributor Defendants would offer sham justifications for filling them – shams that the Drug Producers accepted without question, no matter how ludicrous – thereby giving the producers a convenient pretense to fill an order that they knew would supply the illegal drug market. Through this symbiotic relationship, the Producer Defendants and the Distributor Defendants persisted in filling suspicious orders and/or calling on suspicious subscribers and pharmacies, and shipped drugs to rural Tennessee communities ravaged by the opioid epidemic at levels far exceeding any conceivable need. The Drug Producers and Distributor Defendants knew that their actions would cause (and in fact did cause) increased abuse, addiction, and overdose rates in Tennessee and the Counties at issue in this lawsuit (the “Counties”). They also knew that their actions facilitated illegal drug transactions in Tennessee and the Counties.

12. The Retailer Defendants also committed various acts to facilitate diversion and illegal drug sales. These acts include but are not limited to: financially and professionally incentivizing pharmacists and other pharmacy employees to fill suspicious orders, including pill mill prescriptions, without conducting due diligence; financially and professionally incentivizing pharmacists and other pharmacy employees to violate their professional obligation to withhold filling a prescription absent a legitimate medical purpose and without determining that the drugs were not likely to be abused or diverted; routinely filling suspicious prescriptions; filling prescriptions by Tennessee prescribers that the Retailer Defendants knew were operating pill mills or knew otherwise were over-prescribing opioids that would supply the illegal drug market; filling

prescriptions for individuals that the Retailer Defendants recognized were pill seekers and drug addicts who would abuse and divert the drugs; filling prescriptions despite obvious signs of diversion and/or improper prescription practices, such as frequent prescriptions at an unrealistically high rate, frequent prescriptions at the highest allowable dosages, prescriptions filled by patients for years on end (who plainly were addicted), and prescriptions filled by individuals who engaged in suspect practices just outside the pharmacy immediately upon filling the prescriptions; and otherwise over-supplying Tennessee and the Counties, including rural Tennessee communities, with quantities of highly addictive opioids that far exceeded any conceivable medical need.

13. It is now beyond any reasonable question that defendants' actions caused – and continue to cause – BABY DOE, his birth mother, and thousands of others in Tennessee to become addicted to opioids – an addiction that, as they well knew, was all but certain to occur. It is also beyond question that all defendants are aware that: opioids continue to be over-prescribed in Tennessee – including in the communities at issue in this lawsuit – at levels far beyond what could be medically justified; that a legion of addicts are obtaining pills on the black market or through “pill mills” to satisfy their addiction; that a significant share of the opioids market in Tennessee consists of illegal drug transactions; that they are doing business with pill mills; and that they are knowingly reaping profits from drug sales in the illegal drug market.

14. Defendants' misconduct garnered significant profits. In 2010 alone, opioids generated \$11 billion in revenue for drug companies.⁹ Of that amount, \$3.1 billion went to Purdue

⁹ Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune.com, Nov. 9, 2011. Available at: <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>.

for its OxyContin sales.¹⁰ Opioids are now among the most prescribed class of drugs and the United States' opioid painkiller market is worth an estimated \$10 billion annually.¹¹ According to *Fortune* magazine, the Distributor Defendants are each among the top 15 companies in the 2017 *Fortune* 500: McKesson, No. 5, with \$192 billion in total revenue; AmerisourceBergen, No. 11, with \$122 billion in total revenue; and Cardinal Health, No. 15, with \$122 billion in total revenue.¹² Additionally, the Sackler family, which owns Purdue – a privately held company – was included on Forbes 2015 list of America's Richest Families, coming in at a stunning \$14 billion.¹³

15. Plaintiffs BRYANT C. DUNAWAY, JENNINGS H. JONES, ROBERT J. CARTER, BRENT A. COOPER, and LISA S. ZAVOGIANNIS (collectively, the "District Attorney Plaintiffs") serve as District Attorneys General for, collectively, nineteen (19) counties in Tennessee that have been devastated by the opioid epidemic (the "Counties"). They have filed this lawsuit asserting claims under the Drug Dealer Liability Act ("DDLA") to protect the health, safety, and welfare of the people in the nineteen (19) counties they represent, to protect the babies like BABY DOE who have been harmed by the opioid crisis, and to protect the resources that the counties have had to expend in an effort to cope with the opioid crisis that the Defendants knowingly precipitated and perpetuate to this day.

¹⁰ *Id.*

¹¹ Ariana Eunjung Cha, *The drug industry's answer to opioid addiction: More pills*, The Washington Post, Oct. 16, 2016. Available at: https://www.washingtonpost.com/national/the-drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.html?utm_term=.42e0328ca459.

¹² Erika Fry, *As America's Opioid Crisis Spirals, Giant Drug Distributor McKesson Is Feeling the Pain*, Fortune.com, June 13, 2017. Available at: <http://fortune.com/2017/06/13/fortune-500-mckesson-opioid-epidemic/>.

¹³ Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, Forbes, July 1, 2015. Available at: <https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#4b11d5d375e0>.

II. THE COURT HAS JURISDICTION AND VENUE IS APPROPRIATE

16. Jurisdiction is proper pursuant to Tenn. Code Ann. § 16-10-101, *et seq.*, and Tennessee's Drug Dealer Liability Act, Tenn. Code Ann. § 29-38-101, *et seq.* The Producer Defendants and Distributor Defendants directed their opioids to the Tennessee market, and more specifically the Thirteenth, Sixteenth, Seventeenth, Twenty-Second, and Thirty-First Districts, a region that includes Cumberland County, while the Prescriber Defendants participated in the illegal opioid drug market throughout the Thirteenth, Sixteenth, Seventeenth, Twenty-Second, and Thirty-First Districts and surrounding areas, with knowledge that the illegal opioids they diverted and sold would be used and/or resold within Tennessee. Plaintiff BABY DOE was born in Putnam County, Tennessee. His birth mother used and made unlawful purchases of drugs produced by Purdue, Mallinckrodt, Endo, and Teva in Tennessee and, upon information and belief, distributed in Tennessee by AmerisourceBergen, Cardinal Health, and McKesson and dispensed by Rite Aid and CVS. During both the time in which his birth mother developed an addiction to opioids and while she was pregnant with BABY DOE, Purdue, Mallinckrodt, Endo, and Teva directed their opioids to the Tennessee market through the Distributor Defendants, and Mr. Sackler directed Purdue to engage in misconduct in Tennessee.

17. Venue is proper pursuant to Tenn. Code Ann. § 20-4-101 because Defendants participated in the illegal drug market that resulted in illegal opioids entering Cumberland County, Tennessee, and District Attorney General BRYANT C. DUNAWAY is the prosecuting attorney for the Thirteenth Judicial District, which includes Cumberland County, Tennessee. Additionally, BABY DOE was born in Putnam County, resides in Putnam County, and his birth mother purchased and consumed illegal opioids in Putnam County, which shares a border with

Cumberland County within the Thirteenth Judicial District. The consumption of these illegal opioids directly contributed to BABY DOE's Neonatal Abstinence Syndrome.

III. PARTIES

A. Plaintiffs Include Multiple Elected District Attorneys General and Baby Doe, a Baby Born Dependent on Opioids

18. Plaintiff BRYANT C. DUNAWAY is the elected District Attorney General for the Thirteenth Judicial District. The Thirteenth Judicial District includes Clay County, the City of Celine, Cumberland County, the City of Crab Orchard, the City of Crossville, the Town of Pleasant Hill, DeKalb County, the Town of Alexandria, the Town of Dowelltown, the Town of Liberty, the City of Smithville, Overton County, the Town of Livingston, Pickett County, the Town of Byrdstown, Putnam County, the City of Algood, the Town of Baxter, the City of Cookeville, the Town of Monterey, White County, the Town of Doyle, and the City of Sparta. He brings this civil enforcement action in his capacity as District Attorney General on behalf of the Thirteenth Judicial District, and all political subdivisions therein, including Clay County, the City of Celine, Cumberland County, the City of Crab Orchard, the City of Crossville, the Town of Pleasant Hill, DeKalb County, the Town of Alexandria, the Town of Dowelltown, the Town of Liberty, the City of Smithville, Overton County, the Town of Livingston, Pickett County, the Town of Byrdstown, Putnam County, the City of Algood, the Town of Baxter, the City of Cookeville, the Town of Monterey, White County, the Town of Doyle, and the City of Sparta pursuant to Tenn. Code Ann. §§ 29-38-106 and 29-38-116(a).

19. Plaintiff JENNINGS H. JONES is the elected District Attorney General for the Sixteenth Judicial District of Tennessee. His district includes Cannon County, the Town of Auborntown, the Town of Woodbury, Rutherford County, the City of Eagleville, the City of La Vergne, the City of Murfreesboro, and the Town of Smyrna. He brings this civil enforcement

action in his capacity as District Attorney General on behalf of the Sixteenth Judicial District, and all political subdivisions therein, including Cannon County, the Town of Auborntown, the Town of Woodbury, Rutherford County, the City of Eagleville, the City of La Vergne, the City of Murfreesboro, and the Town of Smyrna pursuant to Tenn. Code Ann. §§ 29-38-106 and 29-38-116(a).

20. Plaintiff ROBERT J. CARTER is the elected District Attorney General for the Seventeenth Judicial District. His district includes: Bedford County, the Town of Bell Buckle, the Town of Normandy, the City of Shelbyville, the Town of Wartrace, Lincoln County, the City of Ardmore, the City of Fayetteville, the Town of Petersburg, Marshall County, the Town of Chapel Hill, the Town of Cornersville, the City of Lewisburg, Moore County, and the City of Lynchburg. He brings this civil enforcement action in his capacity as District Attorney General on behalf of the Seventeenth Judicial District, and all political subdivisions therein, including Bedford County, the Town of Bell Buckle, the Town of Normandy, the City of Shelbyville, the Town of Wartrace, Lincoln County, the City of Ardmore, the City of Fayetteville, the Town of Petersburg, Marshall County, the Town of Chapel Hill, the Town of Cornersville, the City of Lewisburg, Moore County, and the City of Lynchburg pursuant to Tenn. Code Ann. §§ 29-38-106 and 29-38-116(a).

21. Plaintiff BRENT A. COOPER is the elected District Attorney General for the Twenty-Second Judicial District. His district includes: Giles County, the City of Elkton, the Town of Lynnville, the City of Minor Hill, the City of Pulaski, Lawrence County, the Town of Ethridge, the City of Iron City, the City of Lawrenceburg, the City of Loreto, the City of St. Joseph, Maury County, the City of Columbia, the City of Mount Pleasant, the City of Spring Hill, Wayne County, the City of Clifton, the City of Collinwood, and the City of Waynesboro. He brings this civil enforcement action in his capacity as District Attorney General on behalf of the Twenty-Second

Judicial District, and all political subdivisions therein, including Giles County, the City of Elkton, the Town of Lynnville, the City of Minor Hill, the City of Pulaski, Lawrence County, the Town of Ethridge, the City of Iron City, the City of Lawrenceburg, the City of Loreto, the City of St. Joseph, Maury County, the City of Columbia, the City of Mount Pleasant, the City of Spring Hill, Wayne County, the City of Clifton, the City of Collinwood, and the City of Waynesboro pursuant to Tenn. Code Ann. §§ 29-38-106 and 29-38-116(a).

22. Plaintiff LISA S. ZAVOGIANNIS is the elected District Attorney General for the Thirty-First Judicial District. Her district includes: Van Buren County, the Town of Spencer, Warren County, the Town of Centertown, the City of McMinnville, the Town of Morrison, and the Town of Viola. She brings this civil enforcement action in his capacity as District Attorney General on behalf of the Thirty-First Judicial District, and all political subdivisions therein, including Van Buren County, the Town of Spencer, Warren County, the Town of Centertown, the City of McMinnville, the Town of Morrison, and the Town of Viola pursuant to Tenn. Code Ann. §§ 29-38-106 and 29-38-116(a).

23. The counties, cities, and towns of Tennessee's Thirteenth Judicial District, Sixteenth Judicial District, Seventeenth Judicial District, Twenty-Second Judicial District, and Thirty-First Judicial District are collectively referred to herein as the "Counties." Plaintiffs BRYANT C. DUNAWAY, JENNINGS H. JONES, ROBERT J. CARTER, BRENT A. COOPER, and LISA S. ZAVOGIANNIS, who represent the counties, cities, and/or towns in the judicial districts for which they are responsible, are collectively referred to herein as the "District Attorney Plaintiffs."

24. Plaintiff BABY DOE was born with NAS as a result of his exposures *in utero* to illegal drugs, including oxycodone, hydrocodone, Percocet, OxyContin, Roxicodone, Opana, and

other opioids. These drug exposures provide him the right to sue for damages under the Drug Dealer Liability Act (“DDLA”). The Producer Defendants produced these opioids and/or otherwise contributed to the illegal drug market that caused Baby Doe harm, and Mr. Sackler directed Purdue to commit acts that caused Baby Doe harm. The Distributor Defendants distributed these opioids and/or otherwise contributed to the illegal drug market that caused Baby Doe harm. The Retailer Defendants dispensed these opioids and/or otherwise contributed to the illegal drug market that caused Baby Doe harm. The Prescriber Defendants prescribed these opioids and/or otherwise contributed to the illegal drug market that caused Baby Doe harm.

25. Plaintiff BABY DOE brings this action by and through his legal guardian, his adopted mother. Legal Guardians of children exposed to illegal drugs in utero are authorized to bring this action under the Drug Dealer Liability Act. Tenn. Code Ann. § 29-38-106(a)(1).

B. Defendants Include Drug Producers, Distributors, Retailers, Richard Sackler, and Pill Mill Prescribers, All of Whom Participated in Tennessee’s Illegal Drug Market

i. The Drug Producer Defendants

1. Purdue

26. Defendant PURDUE PHARMA L.P., is a limited partnership organized under the laws of Delaware. Defendant PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and Defendant THE PURDUE FREDERICK COMPANY, INC. is a Delaware corporation with its principal place of business in Stamford, Connecticut. Defendants PURDUE PHARMA L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY, INC. are referred to collectively as “Purdue.”

27. In Tennessee and nationally, Purdue is engaged in the production, promotion, and distribution of opioids, including: (a) OxyContin (OxyContin hydrochloride extended release), a

Schedule II opioid agonist¹⁴ tablet first approved in 1995 and marketed by Purdue for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” OxyContin was indicated, or legally approved, for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”; (b) MS OxyContin (morphine sulfate extended release), a Schedule II opioid agonist tablet first approved in 1987 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Purdue knowingly participates in the illegal drug market for opioids.

28. OxyContin is Purdue’s largest-selling opioid. Between 2009 and 2013, Purdue’s national annual sales of OxyContin fluctuated between \$2.47 billion and \$2.99 billion, up approximately four-fold from 2006 sales of \$800 million. When its patent expired in 2013, OxyContin constituted roughly 30% of the entire market for analgesic drugs (painkillers).¹⁵

29. Purdue transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Under Tennessee law, every manufacturer and wholesaler/distributor, before engaging in the manufacture, sale, or distribution of prescription drugs in Tennessee must be licensed by the State of Tennessee Board of Pharmacy. Purdue presently holds at least three (3) Manufacturer/Wholesaler/Distributor licenses in Tennessee. Purdue has a sales force that called on Tennessee prescribers to drive prescriptions and promote its products. Purdue also has called on Tennessee pharmacies that stock and fill orders for those

¹⁴ An opioid *agonist* is a drug that activates certain opioid receptors in the brain. By contrast, an *antagonist* relieves pain by blocking the receptor.

¹⁵ “*Generic OxyContin Pains the FDA*,” Wall Street Journal (April 14, 2013) <https://www.wsj.com/articles/SB10001424127887324345804578422691805851784> (last visited 2/14/18).

pharmacies. Purdue hires employees to service the Tennessee market. For example, Purdue recently posted online that it was seeking a District Business Manager and a Territory Business Manager to operate out of Knoxville, Tennessee. Purdue also directs advertising and informational materials to impact Tennessee physicians and potential users of Purdue products. Purdue established direct relationships with Tennessee prescribers, including calling on Tennessee prescribers and pharmacies. Upon information and belief, the illegal drug market in the Counties included – and continues to include – Purdue branded and generic opioids, including but not limited to the opioids referenced above. Purdue produced and distributed its prescription opioids into Tennessee, the Counties, and the illegal drug market through the Distributor Defendants and the Retailer Defendants.

30. PURDUE PHARMA L.P. can be served through its registered agent: The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, DE 19808. PURDUE PHARMA INC. can be served through its registered agent: The Prentice-Hall Corporation System, Inc., 80 State Street, Albany, NY 12207. THE PURDUE FREDERICK COMPANY can be served through its registered agent: The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, DE 19808.

2. Mallinckrodt

31. Defendant MALLINCKRODT LLC (“Mallinckrodt”) is a Delaware limited liability company with its principal place of business in St. Louis, Missouri.

32. In Tennessee and nationally, Mallinckrodt is engaged in the production, promotion, and distribution of hydrocodone, Roxicodone, and oxycodone, among other drugs. Mallinckrodt manufactured and marketed two branded opioids: Exalgo, which is extended-release hydromorphone (sold in 8, 12, 16, and 32 mg dosage strengths), and Roxicodone, which is

oxycodone (sold in 15 and 30 mg dosage strengths). In 2009, Mallinckrodt, Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. In 2012, Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded products in Tennessee through its own sales force. Mallinckrodt also is a leading producer of generic opioids. These include (*inter alia*), generic products containing oxymorphone, hydromorphone, and hydrocodone. Mallinckrodt markets and sells its products to and through drug distributors (including the Distributor Defendants here), specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers with mail-order pharmacies, hospital buying groups, independent pharmacies, and other retailers. Mallinckrodt has established direct relationships with Tennessee prescribers and pharmacies. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

33. Mallinckrodt transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Mallinckrodt presently holds at least two (2) Manufacturer/Wholesaler/Distributor licenses in Tennessee. Mallinckrodt hires employees to service the Tennessee market. For example, Mallinckrodt has recently advertised for the position of Regional Reimbursement Manager, Neurology, Tennessee/Ohio, to operate out of Cleveland, Ohio and Knoxville, Tennessee. Mallinckrodt also directs advertising and informational materials to impact Tennessee physicians and potential users of Mallinckrodt products. Mallinckrodt has a sales force that called on, and continues to call on, Tennessee prescribers to drive prescriptions

and promote its products. Mallinckrodt also has called on, and continues to call on, Tennessee pharmacies that stock and fill orders for those pharmacies (and/or Distributor Defendants who, in turn, distribute to pharmacies in Tennessee). Upon information and belief, Mallinckrodt also maintains an office located at 1835 Nonconnah Blvd. # 153, Memphis, Tennessee. As described in greater detail below, Mallinckrodt also has a large share of the opioids market in Tennessee and, by extension, a significant share of the illegal opioids market in Tennessee. Mallinckrodt knowingly participates in the illegal drug market for opioids. Upon information and belief, the illegal drug market included – and continues to include – Mallinckrodt branded and generic opioids, including but not limited to the opioids referenced above. Mallinckrodt produced and distributed its prescription opioids into Tennessee, the Counties, and the illegal drug market through the Distributor Defendants and the Retailer Defendants.

34. Mallinckrodt can be served through its registered agent in the United States: CT Corporation System, 120 South Central Avenue, Suite 400, Clayton, Missouri 63105.

3. Endo

35. Defendant ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

36. Defendant ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of ENDO HEALTH SOLUTIONS INC., and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS INC. are referred to collectively as “Endo.”

37. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Tennessee. Endo also produces and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone

products in the U.S. and Tennessee, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Endo's flagship opioid product, Opana ER, yielded \$1.15 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. From 2012 through 2016, Endo continued to realize revenues on sales of Opana ER alone of over \$1 billion.¹⁶ Endo eventually withdrew a reformulated version of Opana ER from the market in July 2017 at the FDA's behest because of widespread abuse and diversion of that product. Within months of that product coming off the market, Endo then entered into a profit-sharing agreement with Impax Laboratories, Inc. to share profits from a generic version of the prior formulation of Opana ER, which Endo had represented in 2012 as so unsafe and subject to abuse and diversion that all sales of the product should be stopped to avert overdose deaths and other "predictable" public health hazards.

38. Endo transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Endo hires employees to service the Tennessee market. For example, Endo recently posted online that it was seeking a District Sales Manager, Pain Management, to operate out of Memphis, Tennessee. Endo also directs advertising and informational materials to impact Tennessee physicians and potential users of Endo products. Endo has a sales force that called on, and continues to call on, Tennessee prescribers to drive prescriptions and promote its products. Upon information and belief, Endo also operates an office at 1910 Danielson Place, Memphis, Tennessee. Endo knowingly participates in the illegal drug market for opioids. Upon information and belief, the illegal drug market included – and continues to include – Endo branded and generic opioids. Endo distributed its prescription opioids into

¹⁶ Endo International PLC FY2014 and FY2016 10-Ks.

Tennessee, the Counties, and the illegal drug market through the Distributor Defendants and the Retailer Defendants.

39. ENDO HEALTH SOLUTIONS INC. can be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. ENDO PHARMACEUTICALS INC. can be served through its registered agent: CT Corporation System, 800 S. Gay Street, Suite 2021, Knoxville, Tennessee 37929.

4. Teva/Cephalon and Associated Companies

40. TEVA PHARMACEUTICALS USA, INC. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. TEVA PHARMACEUTICALS USA, INC. is a wholly owned subsidiary of Teva Pharmaceuticals Industries, Ltd., an Israeli corporation. Cephalon, Inc. is also a wholly owned subsidiary of Teva Pharmaceuticals Industries, Ltd. Hereinafter, TEVA PHARMACEUTICALS USA, INC., Teva Pharmaceuticals Industries, Ltd., and Cephalon, Inc. are collectively referred to as "Teva."

41. Inclusive of companies and products lines it has acquired, Teva develops, markets, and sells prescription drugs, including opioids. In 2011, Teva purchased Cephalon, which was manufacturing a branded opioid called "Actiq" (a branded opioid containing fentanyl) and Fentora (an oral tablet form of fentanyl). Teva marketed and sold both Actiq and Fentora in Tennessee. In 2016, Teva purchased Actavis, which produces generic opioids. In Tennessee and nationally, Teva is engaged in the production, promotion, and distribution of generic opioids, including hydrocodone and oxycodone among other drugs. Teva transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. This includes producing generic opioids that filled millions of prescriptions per year in Tennessee. On its own and/or through front groups and key opinion leaders and otherwise, Teva directs advertising and/or

informational materials to impact Tennessee physicians and potential users of opioids. Teva has employees who service the Tennessee market. Teva knowingly participates in the illegal drug market for opioids. Upon information and belief, the illegal drug market included – and continues to include – Teva branded and generic opioids. Teva distributed its prescription opioids into Tennessee, the Counties, and the illegal drug market through the Distributor Defendants and the Retailer Defendants.

42. Teva can be served through its registered agent: Corporate Creations Network, Inc., 3411 Silverside Road, Tatnall Building, Ste. 104, Wilmington, DE 19810.

ii. Richard Sackler

43. Defendant Richard Sackler is a natural person who resides in Florida. He was on Purdue's Board of Directors and has been involved with Purdue since 1952. As described herein, at all times Mr. Sackler has had a controlling role at Purdue since its founding, and knowingly and intentionally directed Purdue to engage in activities in Tennessee. These include directing Purdue sales representatives and other personnel to detail prescribers in Tennessee to prescribe increasingly high volumes of opioids, directing Purdue to spread misinformation to Tennessee prescribers and patients, and otherwise directing Purdue to do extensive business in Tennessee. Upon information and belief, Richard Sackler personally voted to authorize the 2007 settlement with the Tennessee Attorney General's office, as well as the facts to which Purdue plead guilty in 2007.

iii. Distributor Defendants

1. Amerisource Bergen Drug Corporation

44. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located at 1300 Morris Drive in

Chesterbrook, Pennsylvania 19087. AmerisourceBergen and its affiliates hold multiple wholesaler/distributor licenses in Tennessee.

45. AmerisourceBergen, through various subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes prescription opioids throughout the country, including in the Counties for the Producer Defendants and others. AmerisourceBergen is the second largest pharmaceutical distributor in North America. According to its 2016 Annual Report, AmerisourceBergen is “one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care.” In 2018, AmerisourceBergen was the 11th largest company by revenue in the United States.

46. AmerisourceBergen distributes opioids that are produced by Producer Defendants throughout Tennessee, including opioids within the Counties and the associated illegal drug market. AmerisourceBergen established direct relationships with Tennessee pharmacies, including in the Counties.

47. AmerisourceBergen can be served through its registered agent, the Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. It can be served through its registered agent in Tennessee, CT Corporation System, 300 Montvue Rd, Knoxville, TN 37919.

2. Cardinal Health

48. Defendant Cardinal Health, Inc. is an Ohio Corporation with its principal place of business in Dublin, Ohio. It can be served through its registered agent, CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, OH 43219. Cardinal Health Pharmacy Services, LLC is a Delaware company with a principal office in Ohio. It can be served through its

registered agent, CT Corporation System, 300 Montvue Rd, Knoxville, TN 37919. Cardinal Health Specialty Pharmacy, LLC is a Delaware company with a principal office in Ohio. It can be served through its registered agent CT Corporation System, 300 Montvue Rd, Knoxville, TN 37919. These entities and other affiliates are referred to collectively herein as “Cardinal Health.”

49. Cardinal Health holds multiple wholesaler/distributor licenses in Tennessee.

50. In 2016, Cardinal Health generated revenues of \$121.5 billion.

51. Cardinal Health is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. Additionally, in December 2013, Cardinal Health formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal Health has, at all relevant times, distributed opioids nationwide.

52. Cardinal Health distributes opioids that are manufactured by Producer Defendants throughout Tennessee, including opioids within the Opioid Epidemic Affected Counties and the associated illegal drug market. Cardinal Health established direct relationships with Tennessee pharmacies, including in the Counties.

3. McKesson

53. Defendant McKesson Corporation (“McKesson”) is a Delaware Corporation with its principal place of business located in San Francisco, California. McKesson and its affiliates hold multiple wholesaler/distributor licenses in Tennessee.

54. In its 2017 Annual Report, McKesson states that it “partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.” According to that Report, McKesson “pharmaceutical

distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”

55. McKesson is the largest pharmaceutical distributor in the United States, as well as North America as a whole. McKesson has more than 40,000 customers nationally. McKesson delivers approximately one-third of all pharmaceuticals used in North America. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 billion.

56. McKesson distributes opioids that are manufactured by Producer Defendants throughout Tennessee, including opioids within the Opioid Epidemic Affected Counties and the associated illegal drug market. McKesson established direct relationships with Tennessee pharmacies and dispensing physicians, including in the Counties.

57. McKesson can be served through its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808. It can also be served through its registered agent in Tennessee, Corporation Service Company, 2908 Poston Ave, Nashville, TN 37203.

58. McKesson also had a distribution facility in Memphis from which, upon information and belief, it distributed drugs to pharmacies and dispensing physicians within Tennessee and the Counties.

59. Collectively, McKesson, AmerisourceBergen, and Cardinal Health account for 95 percent of the drug shipments in the United States. These companies together collect about \$400 billion in annual revenue.

iv. Prescriber Defendants

60. Defendant MARK A. MURPHY is a resident of Marshall County, Tennessee. He may be served with process at 2950 Mooresville Hwy, Lewisburg, TN 37091, which is located in the Seventeenth Tennessee Judicial District. He participated in the illegal drug market for opioids.

61. Defendant MONTCLAIR HEALTH & WELLNESS LLC D/B/A SPECIALTY ASSOCIATES ("MONTCLAIR") is a Tennessee limited liability company. Its principal office and mailing address are both 710 Cornersville Road, Lewisburg, TN 37091, which is in Marshall County, TN. It can be served through its registered agent: Edward White, at the same address. MONTCLAIR operates a pain clinic at 710 Cornersville Road, Lewisburg, TN, which participates in the illegal drug market for opioids.

62. Defendant NORTH ALABAMA PAIN SERVICES, LLC ("NAPS"), is an Alabama limited liability company. Its principal office address is 710 Cornersville Road, Lewisburg, TN 37091, which is in Marshall County, TN. It can be served through its registered agent: Defendant MARK MURPHY, at the same address. NAPS operates a pain clinic at 710 Cornersville Road, Lewisburg, TN, which participates in the illegal drug market for opioids.

63. Defendant DAVID FLORENCE is a resident of Coffee County, Tennessee. He may be served with process at 185 Big Falls Circle, Manchester, TN 37355. He participated in the illegal drug market for opioids. Defendant DAVID FLORENCE, the self-proclaimed "DocStar" and focus of the failed Reality-TV show by the same name, is one of the key figures in the opioid epidemic plaguing Plaintiffs' communities. As the owner or operator of numerous "pill mills" in the area, which have freely prescribed opioids without any legitimate medical purpose, he has knowingly, and unlawfully, facilitated the distribution of the powerful and highly-addictive prescription drugs into the illicit market, where they are abused by, and all too frequently kill,

residents of the Plaintiffs' communities. The scope of the epidemic created by "DocStar" Defendant FLORENCE and others cannot be understated. In 2016 alone, there were 1,116,849 prescriptions for opioid painkillers filled in the Plaintiffs' communities, and in only the four-year span between 2012 and 2016 there were a staggering 550 opioid overdose deaths.¹⁷

64. Defendant CENTER FOR ADVANCED MEDICINE, LLC ("CFAM"), is a Tennessee limited liability company. Its principal office address is 804 Keylon St, Manchester, TN 37355, in Coffee County, TN, which borders several counties within the Sixteenth, Seventeenth, and Thirty-First Judicial Districts. It can be served through its registered agent: Jason Huskey, at 514 Hillsboro Blvd, Manchester, TN 37355-1767. CFAM operates a pain clinic at 804 Keylon St, Manchester, TN 37355, which participates in the illegal drug market for opioids.

65. Defendant LYNNVILLE FAMILY MEDICAL CLINIC, LLC ("LYNNVILLE CLINIC") is a Tennessee limited liability company. Its principal office address is 181 Mill St, Lynnville, TN 38472, in Giles County, TN. The entity serves as its own registered agent. LYNNVILLE CLINIC operates two pain clinics, one at 181 Mill St., Lynnville, TN 38472, and another at 118 2nd Avenue South, Lewisburg, Tennessee, which participate in the illegal drug market for opioids.

66. Defendant NATHAN PAUL HASKINS is a resident of Davidson County, Tennessee. He may be served with process at 20 Jones Circle, Old Hickory, TN 37183. He participated in the illegal drug market for opioids.

67. Defendants CFAM, LYNNVILLE CLINIC, MONTCLAIR, NAPS, DAVID FLORENCE, MARK A. MURPHY, and NATHAN PAUL HASKINS are hereinafter collectively

¹⁷ Tennessee Department of Health's Drug Overdose Data Dashboard. Available at: <https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html>.

referred to as the “Criminal Prescriber Defendants.”

68. Upon information and belief, the Drug Producers all called on the Criminal Prescriber Defendants to prescribe more opioids, and the Drug Producers and Drug Distributors filled orders for pharmacies that filled prescriptions written by the Criminal Prescriber Defendants. Upon information and belief, the Drug Distributors supplied the vast majority of pills that filled scripts written by the Criminal Prescriber Defendants.

69. Defendants Purdue, Endo, Mallinckrodt, and Teva are hereinafter collectively referred to as the “Producer Defendants.” The Criminal Defendants, the Drug Distributor Defendants, and the Producer Defendants are hereinafter collectively referred to as “Defendants.”

v. Retailer Defendants

70. Walgreens Boots Alliance, Inc. and Walgreen Co. are Delaware corporations with its principal headquarters and principal place of business located in Deerfield, Illinois (“Walgreens”). Walgreens Boots Alliance, Inc. can be served with process through its registered agent Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808. Walgreen Co. can be served through its registered agent Illinois Corporation Service Company, 801 Adlai Stevenson Drive, Springfield, IL 62701. Walgreens is successor in interest to “Rite Aid.” Rite Aid Corporation is a Delaware corporation with its principal headquarters and principal place of business located in Camp Hill, Pennsylvania. Rite Aid Headquarters Corp. is a Delaware corporation with a principal place of business in Camp Hill, Pennsylvania, that can be served with process through its registered agent in Tennessee, CT Corporation System at 300 Montvue Rd, Knoxville, TN 37919. Rite Aid of Tennessee, Inc. is a Tennessee corporation with a principal place of business in Knoxville, TN, that can be served through its registered agent in Tennessee, CT Corporation System, Knoxville, TN 37919. Plaintiffs refer to these entities and the associated

retail pharmacy stores collectively as “Rite Aid” herein.

71. CVS Health Corporation is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a Rhode Island corporation with its headquarters and principal place of business in Woonsocket, Rhode Island, which can be served with process via its registered agent in Tennessee, CT Corporation System at 300 Montvue Rd, Knoxville, TN 37919. CaremarkPCS Health, L.L.C. d/b/a CVS Caremark is a Delaware corporation with a principal place of business in Woonsocket, Rhode Island, which can be served with process via its registered agent in Tennessee, CT Corporation System at 300 Montvue Rd, Knoxville, TN 37919. Plaintiffs refer to these entities and the associated retail pharmacy stores collectively as “CVS” herein.

72. Rite Aid and CVS (collectively, the “Retailer Defendants”) are engaged in the business of retail selling of opioids. They are collectively referred to herein as the “Retailer Defendants.” Upon information and belief, the Retailer Defendants knowingly filled suspicious orders and improper prescriptions, and also utilized a perverse incentive system for their employees that incentivized pharmacists to fill suspicious orders.

73. The Retailer Defendants operate various retail pharmacies in Tennessee, conducted business in Tennessee, and purposely directed their actions towards Tennessee. They also have a registered agent for service of process in Tennessee and hold Tennessee licenses to dispense prescription drugs, including the opioids at issue in this lawsuit, within Tennessee. The Retailer Defendants dispensed many of the opioids at issue in this lawsuit, including opioids produced the Producer Defendants, distributed by the Distributor Defendants, and prescribed by the Prescriber Defendants. The Retailer Defendants’ activities within the Counties and directed at the Counties are continuous and systematic, giving rise to the claims asserted herein.

IV. SCIENTIFIC BACKGROUND

A. **Opioids Have Never Been Proven Appropriate for Long-Term Chronic Pain and Other Non-Acute Medical Problems**

74. This case primarily, but not exclusively, concerns the following four types of opioids:

- a. Oxycodone: Oxycodone is a powerful type of opioid. It can be prescribed as oxycodone or more specifically branded by a company, such as OxyContin or Roxicodone.
- b. Hydrocodone: Hydrocodone is also a type of opioid. It can be prescribed as hydrocodone or more specifically branded by a company, such as Lortab or Vicodin.
- c. Oxymorphone: oxymorphone is also a type of opioid. It can be prescribed as oxymorphone or more specifically branded by a company, such as Opana and Opana ER.
- d. Hydromorphone: Hydromorphone is also a type of opioid. It can be prescribed as hydromorphone or more specifically branded by a company, such as Exalgo.

75. The scientific consensus is that opioids such as these are dangerous, highly addictive, and inappropriate for long-term chronic pain – as opposed to cancer pain and pain associated with surgery and acute injuries. This opinion existed in the mid-1990s and has never been challenged in any meaningful way with new, valid scientific evidence.

76. The National Safety Council, a not-for-profit organization chartered by Congress to improve public health, has published a summary of research titled “Evidence for the Efficacy of Pain Medications”¹⁸ The National Safety Council report concludes that “[d]espite the widespread use of opioid medications to treat chronic pain, there is no significant evidence to support this practice.”¹⁹

¹⁸ Donald Teater, Nat’l Safety Counsel, *Evidence for the Efficacy of Pain Medications*, 3 (2014) [hereinafter *Evidence for Efficacy*].

¹⁹ *Id.* at 6 (emphasis added).

77. Multiple researchers have found that “no evidence exists to support long term use – longer than four months – of opioids to treat chronic pain.”²⁰

78. A 2013 review of existing literature by Dr. Igor Kissin of the Department of Anesthesiology, Perioperative, and Pain Medicine at Brigham and Women’s Hospital, Harvard Medical School, concluded that “[n]ot a single randomized controlled trial with opioid treatment lasting [greater than] 3 months was found.”²¹

79. The same review found that “[a]ll studies with a duration of opioid treatment [greater than or equal to] 6 months were conducted without a proper control group.”²²

80. Dr. Kissin further concluded that “[t]here is no strong evidence-based foundation for the conclusion that long-term opioid treatment of chronic malignant pain is effective.”²³

B. Opioids Carry a High Risk of Addiction, Serious Medical Problems, and Death

81. Opioids have severe side effects, including: gastrointestinal bleeding, impaired recovery from injury or surgery, cognitive impairment, respiratory depression, endocrine abnormalities, hyperalgesia (increased sensitivity to pain), increased risk of fractures and hospitalization for the elderly, addiction, and death.²⁴

82. Research based on actual patient interviews has found that, **among patients who received four or more prescriptions in the prior year, 35% met the criteria for a lifetime**

²⁰ *Id.* (citing multiple publications).

²¹ Igor Kissin, *Long-term Opioid Treatment of Chronic Nonmalignant Pain: Unproven Efficacy and Neglected Safety?*, 2013:6 J. Pain Research 513, 513 (2013), available at <https://www.dovepress.com/long-term-opioid-treatment-of-chronic-nonmalignant-pain> *unproven-ef-peer-reviewed-article-JPR*.

²² *Id.*

²³ *Id.*

²⁴ Donald Teater, Nat’l Safety Council, *The Psychological and Physical Side Effects of Pain Medications*, 2-6 (2014) (summarizing side effect data). [hereinafter *Side Effects*]

opioid dependence, and 25.8% met the criteria for current opioid dependence.²⁵

83. Dr. Nora D. Volkow and Dr. Wilson M. Compton, the Director and Deputy Director of the National Institute of Drug Abuse at the National Institute of Health, respectively, co-authored a 2006 study that concluded: “[t]hrough the use of opioid analgesics for the treatment of acute pain appears to be generally benign, **long-term administration of opioids has been associated with clinically meaningful rates of abuse or addiction.**”²⁶

84. Consistent with this finding, a 2011 review of medical and pharmacy claims records revealed that two thirds of patients who took opioids daily for ninety days were still taking opioids five years later.²⁷

85. Researchers evaluating opioids for treatment following lumbar disc herniation likewise found that giving such patients opioids had no effect on treatment outcome, but significantly increased their risk for long term opioid addiction.²⁸

86. Dr. Mitchell H. Katz, current director of the Los Angeles County Health Agency, has described how patients with nonmalignant conditions can end up as drug addicts because of the prescribing of opioids:

A certain number of patients get better with NSAIDs [non-steroidal anti-inflammatory drugs, like Tylenol].... For those still complaining of pain, you next prescribe a short-acting opioid with a relatively low potency, such as acetaminophen with codeine. ... You tell them about the adverse effects of opioids and encourage them to use the lowest dose necessary. Not infrequently, at the next

²⁵ Joseph A. Boscario, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy*, 2015:6 Substance Abuse and Rehabilitation 87, 87-89 (2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/>.

²⁶ Wilson M. Compton et al., *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 Nat’l Inst. on Drug Abuse 103, 103-07 (2006).

²⁷ Bradley C. Martin et al., *Long-term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) J. Gen. Intern. Med. 1450, 1450-57 (2011).

²⁸ Evidence for Efficacy at 5 (citing Radcliff et al., *Does Opioid Pain Medication Use Affect the Outcome of Patients with Lumbar Disk Herniation?*, 38(14) The Spine J. E849, E849-60 (2013)).

visit they tell you that the medicine works but that they are taking the pills more frequently than directed. At this point, you worry about liver damage from the acetaminophen and switch to a higher potency, longer acting agent. The patient returns for follow-up visits and tells you that the pills work but that they sometimes take an extra pill and could you please increase the number so they “don’t run out before the next visit.” Before you know it, the patient is on a high dose of an opioid, and you are unsure whether you have actually helped them. **What you know is you have committed yourself to endless negotiations about increasing doses, lost pill bottles, calls from emergency departments, worries that your patient is selling the drugs, and the possibility that one day, your patient will take too many pills, perhaps with alcohol, and overdose.**²⁹

V. MATERIAL FACTS

A. **Overview: The Defendants Created the Illegal Drug Market Through Unlawful Distribution and Otherwise Knowingly Supplied and Knowingly Participated in the Illegal Drug Market in Tennessee**

87. The Producer Defendants, Drug Distributor Defendants, Retailer Defendants, and Prescriber Defendants all participated in the illegal drug market in Tennessee and capitalized on it. Each played a knowing role in creating, perpetuating, and expanding the opioid crisis.

88. Controlled substances are, by definition, highly subject to abuse and diversion. For this reason, Tennessee regulates every participant in the chain of distribution. No one can distribute or dispense prescription opioids in Tennessee without maintaining effective controls against diversion and ensuring that the drugs are serving a lawful medical purpose. Indiscriminate distribution without sufficient controls is unlawful and can lead to criminal penalties in Tennessee.

89. The Producer Defendants, Distributor Defendants, and Retailer Defendants have used their registration certificates with Tennessee as cover for what is essentially a criminal enterprise. They knowingly distributed drugs in Tennessee without diversion controls, conscious that they were feeding pill mills and the black market rather than legitimate medical need. That

²⁹ Mitchell H. Katz,, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Arch Intern. Med. 1422, 1422-24 (2010).

conduct was unlawful. Even in isolation, it subjects them to liability under the DDLA.

90. But the problem was much, much worse than that. The Producer Defendants purposely created the illegal market for their own products by successfully convincing prescribers to prescribe opioids in high volumes, high dosages, and with such frequency that the patients quickly (and inevitably) would become addicted – as defendants knew would happen. They devised every way imaginable to guarantee this result. This included lying to prescribers about the risk profile of their opioids (to which Purdue plead guilty), spreading disinformation about how addictive their drugs were, and targeting with surgical precision the highest-volume prescribers to convince them to prescribe more opioids – knowing that those prescribers were operating and were likely to be operating pill mills. They established direct relationships with pharmacies that supplied pill mills. They flooded small Tennessee communities with opioids at levels that their own experts determined was resulting in diversion – filling the very prescriptions that they convinced corrupt prescribers to make, to feed the addicts and pill seekers that they had addicted to their drugs. They hired large sales forces, rewarded them for doing business with pill mills, and penalized them for missing sales targets. When the government directed them to implement effective controls against diversion, they purposely created sham “suspicious order monitoring” programs that were structured to fail and structured to allow them to ship opioids into known diversion channels. This entire system was a criminal chain of distribution from start to finish. As the DEA determined relative to Mallinckrodt, this malfeasance made the Producer Defendants “kingpins” in a drug cartel.

91. The Drug Distributor Defendants and Retailer Defendants also participated in this enterprise and abused their authority. They knew who the pill mill operators were and knew when the level of drugs into these communities was feeding the illegal drug market. But like the

Producer Defendants, they purposely did not implement meaningful diversion controls, incentivized their employees to service pill mills, and reaped handsome profits from the flow of drugs into the black market. They distributed and dispensed these drugs unlawfully, and otherwise knowingly facilitated illegal prescription opioids sales.

92. At every step, these defendants sought to stream drugs to the illegal market, to continue over-supplying Tennessee communities at levels that were not medically justifiable and enjoy profits derived from the illegal distribution of opioids. They continue to do so to this day.

B. The Producer Defendants and Distributor Defendants All Have Participated in the Distribution Pipeline for Opioids in Tennessee and in the Counties

i. The Drug Producers Possessed Information Reflecting Diversion by Prescribers and Pharmacies, But Facilitated that Diversion Anyway

93. As described herein, the Producer Defendants, Distributor Defendants, and Retailer Defendants did not maintain effective controls against diversion, rendering their actions illegal, and they otherwise engaged in many other acts to facilitate diversion of their drugs illegally. They also plainly undertook actions in Tennessee or directed at Tennessee that they knew were detrimental to public health and safety.

94. The related crises of abuse and illegal diversion of prescription opioids in Tennessee is well-documented in a variety of publicly available sources. Indeed, the prescription statistics reflect how the Producer Defendants and Distributor Defendants each are participating in the unconscionable flow opioids into East Tennessee.

95. Through their market research and extensive networks of sales representatives and face-to-face detailing of health care providers (“HCP”), Purdue, Mallinckrodt, Endo, and Teva could, and did, observe signs of illegal diversion. Readily observable indications of illegal diversion, and even drug dealing, include, but are not limited to:

- An apparent pattern of an excessive number of patients for the practice type. For example, on a consistent basis, a long line of patients waiting to get prescriptions, a waiting room filled to capacity or standing room only, or patient contact with a prescriber that is exceedingly brief or non-existent.
- A HCP who has a disproportionate number of patients who pay cash for office visits and dispensed medication.
- A HCP with a sudden unexplained change in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or the practice type.
- A HCP's practice where unauthorized individuals are signing prescriptions or dispensing controlled substances.
- HCP's practice where drugs or doses are not being individualized.
- A HCP with a lack of qualified staff, such as registered nurses or nurse practitioners.
- A HCP's practice with large numbers of patients who travel significant distances, for example across state lines, to obtain and/or fill their prescriptions without a rational explanation.
- A HCP's practice where there are reports that patients make frequent early requests for new prescriptions significantly in advance.
- An HCP who moves his or her practice from one state to another on more than one occasion within a couple of years without rational explanation.

96. Upon information and belief, and as described further herein, Purdue, Endo, Mallinckrodt, and Teva also received information from credible sources – including, but not limited to, pharmacists and law enforcement agencies – that an HCP or his or her patients were diverting prescription medication.

97. Upon information and belief, and as described further herein, Purdue, Mallinckrodt, Endo, and Teva each maintained an internal database of HCPs suspected of inappropriately prescribing opioids. HCPs could be added to the database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills. In particular, Purdue, Mallinckrodt, Endo, and

Teva tracked HCPs' prescribing practices using data obtained from IMS Health, which allowed them to identify HCPs writing excessively large numbers of prescriptions, particularly for high doses, which is a potential sign of diversion and drug dealing.³⁰

98. Purdue, Mallinckrodt, Endo, and Teva also possess information called "chargeback" data from their distributors. As reported in the Washington Post, there is an "industry-wide practice" whereby pharmaceutical drug producers pay their distributors rebates and/or "chargebacks" on prescription opioid sales.³¹ In return, the distributors provide Purdue, Mallinckrodt, Endo, and Teva with downstream purchasing information, which allows them to track their prescription opioids down the entire supply chain, all the way to the retail level.³²

99. Using chargeback data, Purdue, Mallinckrodt, Endo, and Teva knew – just as the prescription opioid distributors knew – the volume, frequency, and pattern of prescription opioid orders being placed and filled. From that data, they knew or recognized which orders were suspicious and indicative of diversion in Tennessee and elsewhere. However, they continued to fill orders relative to those accounts (including pharmacies and dispensing physicians) for their drugs, despite knowing that the orders were suspicious and indicative of diversion, that the pharmacies to whom the orders were shipped were engaging in suspicious practices indicative of diversion, and/or that the pharmacies were filling orders from pill mills and other high-volume prescribers engaged in suspicious prescribing practices. To make matters worse, the Producer Defendants used this chargeback data for sales purposes to identify the highest volume prescribers and highest-volume pharmacies as *sales targets*. Many of these targets were located in rural Tennessee communities with a thriving illegal drug market and an obvious over-supply issue. In

³⁰ Ryan, *More than 1 million OxyContin pills*.

³¹ See Bernstein, *The government's struggle*.

³² *Id.*

this way, the Producer Defendants knowingly facilitated the illegal diversion of prescriptions by (*inter alia*) suspicious prescribers and pharmacies, enabled the illegal diversion of prescription opioids, aided criminal activity, and otherwise facilitated the dissemination of massive quantities of prescription opioids into the black market.

100. Tennessee regulates the distribution of controlled substances. Under Tennessee law, prescription opioids are “Schedule II” controlled substances because they inherently have a “high potential for abuse” and that “may lead to severe psychic or physical dependence.”³³ For this reason, everyone who handles prescription opioids in Tennessee (from production to retail sales) must maintain appropriate safeguards against abuse and diversion, and must register with the State and must ensure that the drugs are only being distributed to serve legitimate medical purposes.³⁴ If either or both of these preconditions is not satisfied, it is unlawful to distribute prescription opioids in Tennessee. Indeed, entities holding a Tennessee license can be criminally prosecuted for violating their responsibilities in the distribution chain.³⁵ Defendants violated these preconditions and acted unlawfully.

ii. Purdue’s Misconduct Places it Squarely at the Center of the Opioid Epidemic Ravaging the Opioid Epidemic Affected Counties

101. After helping to create the opioid epidemic, Purdue has worked to sustain that illegal opioids market and to continue profiting from it.

102. There were nearly *twelve million* (11,788,252) prescriptions of popular branded and generic opioid products containing hydromorphone, oxymorphone, oxycodone, and

³³ T.C.A. § 39-17-407.

³⁴ See, e.g., T.C.A. § 53-11-302 and -303; Rules of Tn Bd. of Pharmacy, Ch. 1140-02.01 *et seq.* and Ch. 1140-09.01 *et seq.*

³⁵ See T.C.A. § 53-11-401(1).

hydrocodone in the State of Tennessee for the 24-month period of September, 2015 through August, 2017 according to IMS data.

103. Purdue's average market share of oxycodone in Tennessee from 2015 to 2017 was nearly 5%, led by its popular brand product OxyContin.

104. Purdue knows exactly how much of its product flows into the Counties. On the heels of its 2007 plea agreement, Purdue approached wholesalers and struck agreements allowing the company access to their sales reports. This data allowed Purdue's security team to track all wholesalers' OxyContin sales to individual pharmacies, down to the pill.³⁶

105. Purdue is also put on notice, when OxyContin is likely being diverted in the Counties, and can react by halting shipments into the affected areas. In July 2016, Purdue's general counsel acknowledged that the company is "required to monitor and report suspicious orders to the DEA," and that while Purdue cannot halt shipments to suspect pharmacies, they "can and have reduced the product they ship to a wholesaler if they have concerns about the customer at the end of the supply chain."³⁷

106. Purdue tracked physicians' prescribing practices by reviewing pharmacy prescription data it obtained from IMS Health. Rather than reporting highly suspicious prescribing practices, Purdue used the data to identify physicians who prescribed some opioids and might be persuaded to prescribe more.³⁸

³⁶ Harriet Ryan, *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, L.A. Times (July 10, 2016). Available at: <http://www.latimes.com/projects/la-me-oxycontin-part2/>. [hereinafter "Ryan, *More than 1 million OxyContin pills*"].

³⁷ *Id.*

³⁸ *Id.*

107. Using IMS Health data, Purdue also could identify physicians writing large numbers of prescriptions, and particularly for high-dose 80 mg pills – potential signs of diversion and drug dealing.³⁹ An 80 mg tablet is equivalent in strength to 16 Vicodin tablets, and was generally reserved by doctors for patients with severe, chronic pain who had built up a tolerance over months or years. In the illegal drug trade, however, “80s” were the most in demand. For those attempting to detect how OxyContin was getting onto the black market, a physician writing a high volume of 80s was a red flag.⁴⁰

108. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from sales representatives and, in some instances, its own surveillance operations.⁴¹ A 2013 article in the L.A. Times – which was based on a review of court and law enforcement records, including internal Purdue documents, and interviews with current and former Purdue employees – revealed that, since at least 2002, Purdue has maintained a database of 1,800 doctors suspected of recklessly prescribing the company’s pills to addicts and drug dealers.⁴² Purdue refers to the confidential list as “Region Zero” in internal documents.⁴³ In all but a few cases, Purdue did not alert law enforcement or medical authorities to the doctors on its list, many of whom were prolific prescribers of OxyContin.⁴⁴

109. The example of Dr. Eleanor Santiago, one of the physicians on Purdue’s “Region Zero” list, provides a stunning display of the causal relationship between the prescription market

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ Scott Glover, *et al.*, *OxyContin Maker Closely Guards Its List of Suspect Doctors*, latimes.com, Aug. 11, 2013, <http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811>. [hereinafter “Glover, *OxyContin Maker*”]

⁴⁴ *Id.* (noting that Purdue purportedly alerted law enforcement or medical regulators to 154 of the suspected prescribers – about 8% of those in its database).

and diverted market for OxyContin, as well as Purdue's willful and knowing decision to profit from the diversion problem.⁴⁵

110. Beginning in the summer of 2008, Dr. Santiago, an elderly physician, ran the Lake Medical "clinic" (set up by an ex-con and his business partner) out of an office space on a seedy block near MacArthur Park in Los Angeles.⁴⁶ Dr. Santiago immediately began prescribing OxyContin in "extraordinary quantities."⁴⁷ In a single week in September 2008, she issued orders for 1,500 pills, which is more than entire pharmacies sold in a month.⁴⁸ By October of that year, it was 11,000 pills, and by December, she had prescribed more than 73,000 pills, with a street value of nearly \$6 million.⁴⁹

111. Purdue tracked the surge in prescriptions, zeroing in on the prescriptions of 80-mg, maximum-strength OxyContin written by Dr. Santiago.⁵⁰ As the L.A. Times article explains: "The number of prescriptions Santiago was writing wasn't merely high. It was jaw dropping. Many doctors would go their entire careers without writing a single 80s prescription. *Santiago doled out 26 in a day.*"⁵¹

112. Eventually, Purdue dispatched Michele Ringler, the district sales manager for Los Angeles, to check out the clinic as part of the company's investigation. When Ringler and one of her sales reps arrived, they found a building that looked abandoned, according to company emails recounting the visit. Inside, the hallways were strewn with trash and lined with a crowd

⁴⁵ See Ryan, *More than 1 million OxyContin pills*.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.* (emphasis added).

of men who looked like they “just got out of L.A. County jail.” Feeling uncomfortable, Ringler and the rep left without speaking to Dr. Santiago.

113. When a Purdue security committee met in Stamford in December 2008, less than five months after Lake Medical opened, Dr. Santiago was under review, according to internal records and interviews. The panel, comprised of three company lawyers, could have reported Dr. Santiago to the DEA. Instead it opted to add her name to the “Region Zero” list of physicians suspected of recklessly prescribing OxyContin to addicts or dealers.

114. As Purdue’s investigation of the clinic continued, the company eventually concluded that Lake Medical was working with a corrupt pharmacy in Huntington Park to obtain large quantities of OxyContin. In a September 1, 2009 email Ringler sent to company officials, she referred to the Lake Medical clinic and corrupt pharmacy as “an organized drug ring,” and suggested that Purdue contact the DEA.⁵² Nevertheless, Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang, and other criminals.⁵³

115. Dr. Santiago’s case is just one of many that demonstrate that Purdue did not use its database of suspected physicians to reduce OxyContin abuse, to rein in dangerous physicians, or to stop the unlawful distribution of opioids. Instead, Purdue knowingly aided criminal activity in order to maximize its own profits.

⁵² *Id.*

⁵³ *Id.*

116. As part of its investigation, the L.A. Times conducted several interviews with Jack Crowley, a former Supervisory Investigator at the DEA who served as the Executive Director of Controlled Substances Act compliance at Purdue until retiring in 2013.⁵⁴ Throughout the course of the interviews, Crowley said that “in the five years he spent investigating suspicious pharmacies, *Purdue never shut off the flow of pills to any store.*”⁵⁵ According to Crowley, “[p]harmacies were allowed to buy OxyContin even in cases when Purdue security staffers personally witnessed suspicious behavior.”⁵⁶ For example, at two San Francisco pharmacies, Crowley personally observed “homeless people filling prescriptions and then handing the bottles off to men he suspected were drug dealers,” but Purdue continued to supply the unscrupulous pharmacies.⁵⁷ As this and other examples illustrate, “even when [Purdue] had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores.”⁵⁸

iii. Purdue’s Business Model Is Designed to Distribute Drug Unlawfully and Otherwise to Facilitate Diversion

117. Purdue’s business model was predicated on convincing prescribers, including Tennessee prescribers, to issue more prescriptions for Purdue products. Through its sales representatives, Purdue established direct relationships with Tennessee prescribers, through which it actively detailed doctors to get them to prescribe more opioids. Purdue gave commission-based bonuses to sales representatives that gave the sales representative one over-arching goal: convince prescribers to prescribe even more.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

118. In service of that goal, Purdue determined that frequently contacting prescribers was effective at driving sales. Purdue determined that *not* frequently contracting prescribers would result in approximately 75% fewer opioid prescriptions from high-volume prescribers. Upon information and belief, the other Producer Defendants also made the same determination.

119. Purdue therefore intentionally targeted its highest volume prescribers to get them to prescribe even more opioids. It placed special emphasis on targeting pain management clinics. It did so even when it was readily obvious that by doing so, it was facilitating diversion and illegal drug transactions by doing business with pill mills and other over-prescribers.

120. For example, Purdue determined, through what it termed the “80/20” effect, that the top 20% of its prescribers accounted for approximately 80% of its OxyContin prescriptions. Purdue accordingly “deciled” the prescribers (namely, sorting them by decile from highest-prescribing to lowest) – and specifically targeted highest prescribers and practices to get them prescribe even more. With few exceptions, the highest-volume prescribers were prescribing opioids at prodigious rates that far exceeded any conceivable medical need and that plainly reflected abuse and diversion. Many of those prescribers ultimately had their licenses revoked, were arrested, or were otherwise identified by the government as having actively supplied drugs to the illegal drug market.

121. Using IMS Health data, its own sales information, and other sources, Purdue also categorized top prescribers of extended release opioids (or top potential prescribers) as “Core” (high volume) and “SuperCore” (the highest volume). These prescribers were the ones who issued the most scripts nationwide and whom Purdue therefore believed would be most susceptible to sales and marketing by Purdue to prescribe more opioids or to switch from less potent (and less addictive) analgesics to OxyContin. Many of those prescribers were located in Tennessee,

including at offices that served the Counties and surrounding areas. Purdue utilized the categorization of “Core” and “SuperCore” as accolades, not warning signs. It praised sales associates for calling on these highest volume prescribers, incentivized sales associates to call on them even more, and used these categorizations to drive more prescriptions for its opioids, particularly OxyContin. As described herein, this included calling on prescribers in rural Tennessee communities who were prescribing opioids at prodigious rates that far exceeded any community need.

122. Purdue knew exactly where its pills were going, who was prescribing them, who was filling them, and in what volumes. It compiled this information through its direct relationships with prescribers and pharmacies, with chargeback data from its distributors (including the Distributor Defendants), from IMS Health data, and from other sources. Rather than use this information to identify and report suspicious orders, it instead used the information to drive OxyContin sales as high as it could get them.

123. Purdue also devised additional ways to promote OxyContin sales. For example, it provided OxyContin vouchers or savings cards to prescribers to give to patients, which patients could redeem when purchasing the drugs at a retailer. Also, upon information and belief, Purdue had a replacement program for pharmacies whose inventories of Purdue opioid products were stolen or robbed that supplemented any amount of loss not covered by the pharmacy’s insurance company. Purdue presented before the Governor’s Working Group on or about September 11, 2015. At that presentation, Purdue conceded that “[t]he abuse of prescription opioid analgesics in the US is a significant public health problem,” conceded that “OxyContin ... is subject to misuse, addiction, and criminal diversion,” and conceded that even after the creation of purportedly abuse-resistant OxyContin, “abuse by these routes [injection and nasal], as well as the oral route, is still

possible.”

124. Purdue knew that high prescription volumes correlate with diversion. In the early 2000s, it identified the top 200 prescribers of OxyContin nationwide and identified counties with the highest prescription rates, including prescribers and counties in Tennessee. It used *per capita* prescription rates as a proxy for likely abuse and diversion, and determined that those areas required special attention and targeted efforts to educate prescribers about the risks of over-prescribing. However, perhaps recognizing that clamping down on its highest prescribers would cut off its own revenue stream, Purdue abandoned this effort. Instead, it ultimately chose to continue promoting OxyContin to the same degree and in the same way in Tennessee as the rest of the country.

125. Abandoning diversion control for diversion facilitation, Purdue assisted the prescribers who were most likely to be creating addicts and fostering the illegal drug market by *encouraging them to prescribe even more*. When Purdue targeted high-volume prescribers, it did so without regard to (and without determining) what a medically appropriate level of prescribing would be. The primary criterion was driving the number of prescriptions ever higher – regardless of what it knew and what information it learned.

126. Accordingly, Purdue continued to make sales calls and to offer these types of promotions in spite of credible reports of suspicious behavior and adverse reactions in Tennessee and elsewhere, including patient overdoses, indictments, adverse licensure actions, a provider admitting he was addicted to heroin, a knife fight outside of a provider’s office, muggings over controlled substances outside of a pharmacy linked to a specific provider, a clinic that had no examination tables or equipment, an admission by a provider that he was running a pill mill, a provider changing the name of his practice shortly after he was notified of a state investigation

into his practice, a patient being coached in the waiting room about how to fill out intake forms, armed guards in provider waiting rooms, high numbers of patients who purchased OxyContin in cash, high numbers of out-of-state or out-of-country tags in providers' parking lots, accusations of insurance fraud, choreographed urine screenings and pill counts, standing-room-only waiting rooms, and additional signs of problematic high volume practices.

127. Following the 2007 settlement with the Tennessee Attorney General's Office, Purdue also was required to implement an effective system for abuse detection and reporting. Purdue knew that its actions were inappropriate and facilitated diversion. It recognized that it had a responsibility to detect and report suspicious practices and suspicious orders. In spite of that recognition and obligation, it implemented "diversion detection" programs that were structurally designed to fail so that abuse and diversion would continue unimpeded.

128. Purdue superficially directed its sales representatives to report signs of abuse and diversion. However, Purdue purposely disincentivized abuse detection and otherwise supplied prescribers and practices even after receiving notice of diversion. Purdue essentially entrusted sales representatives to be the company's sole source to detect and report abuse and diversion, but simultaneously (and purposely) incentivized those sales representatives *not* to report pill mills or over-prescription practices. Sales representatives and their supervisors understood that it was against their financial interests to report high-volume prescribers engaging in abuse, diversion, and over-prescribing, because the high-volume prescribers generated the most sales. Purdue intentionally incentivized sales representatives not to report pill mills or over-prescription practices internally.

129. In addition to providing financial incentives for its sales force to prioritize sales volume over any other criterion, Purdue also took other measures to ensure that sales

representatives did not report suspicious prescribers:

- a. Purdue superficially gave its sales force a list of a criteria for reporting suspicious practices. However, it did not explain what those criteria meant, did not explain how to apply them, did not follow up to see if sales representatives actually understood or applied them in practice, and did not evaluate sales representatives in any fashion based on their ability or effectiveness to detect and report diversion. It simply provided the sales representatives a list of factors and gave them *carte blanche* to ignore the criteria.
- b. To ensure that the sales force understood that there would be no consequences for ignoring the abuse and detection criteria in practice, Purdue did not penalize anyone in the sales force (or otherwise retroactively rescind commissions) for calling on prescribers whom the government later determined had operated a pill mill that fed the illegal drug market, for calling on prescribers who were disciplined by Tennessee medical licensing boards, or for calling on pharmacies that got in trouble for supplying pill mills.

130. Not surprisingly, Purdue sales representatives (with Purdue's knowledge) generally ignored Purdue's stated criteria for reporting suspicious prescribers and suspicious orders, and continued to call on those customers even where red flags were present.

131. Incredibly, even in the limited instances where sales associates did identify red flags, Purdue gave sales representatives the option *not* to report the subscriber through Purdue's formal abuse detection program. Rather than formally report the red flag, sales representatives had the option to identify the red flags in "call notes" that remained within the sales department and generated no additional scrutiny.

132. Purdue designed these measures to fail. Accordingly, the sales force actively called on high-volume Tennessee prescribers and practices despite obvious signs of diversion, such as professional disciplinary action or law enforcement actions against a prescriber or practice, a gross disparity between the number of prescriptions and the local population served, public news reports of diversion, the presence of young people milling about outside the practice, the presence of out of state license plates at the facility, practices that accepted only cash payments, practices that

accepted only excessive fees for the drugs, and the like. Purdue called on prescribers after their former practices were raided by the FBI. It called on prescribers after Tennessee accused prescribers of professional misconduct. It called on prescribers who had no actual, local supervising physician. The sales force never reported any provider to law enforcement – in Tennessee or elsewhere.

133. Purdue had a suspicious order monitoring committee, but took actions to ensure that the committee cut off as few customers and suspicious orders as possible. First, as described above, it came up with measures to ensure that as few reports reached the committee's attention as possible. In those limited instances in which the committee actually received a report of concern or a request from law enforcement, Purdue acted in other creative ways to avoid stemming the flow of pills to high-prescribing Tennessee pill mills.

- a. For example, when presented with evidence of diversion by a pill mill, Purdue would "investigate" the prescriber or pharmacy supplier *ad infinitum* while authorizing sales representatives to continue to call on those prescribers to drive more sales. Often, Purdue intentionally continued to call on those prescribers to prescribe Purdue opioids (or the pharmacy to continue filling those prescriptions) until a federal or state government either arrested the prescriber or shut the practice down.
- b. At times, the committee would receive a report but not act on it.
- c. Purdue allowed sales representatives to call on reported pharmacies and subscribers before an investigation was complete (or even initiated).
- d. Purdue knew that certain physicians nominally oversaw prescription practices by non-physicians at multiple clinics at the same time. When those physicians were individually disciplined or arrested, or where Purdue otherwise had no choice but to cease calling on them, Purdue's committee would place that lone physician on its "no call" list but allow sales representatives continue to call the pill mill operation overseen by the physician.

Purdue undertook these types of actions relative to Tennessee prescribers and pharmacies.

134. Purdue also employed other means to facilitate diversion:

- a. It called on pain management clinics and pushed them to prescribe more opioids, without verifying that they were even certified as required by Tennessee law. (T.C.A. § 63-1-301 *et seq.*)
- b. It urged non-physician prescribers to prescribe more opioids, even where (in violation of Tennessee law) there was no actual supervising physician.
- c. It urged prescribers to write more OxyContin prescriptions even after it received a report of potential diversion, choosing to continue to target them and urge them to prescribe more, rather than suspend calling while an investigation was pending.
- d. After initially placing a suspect prescriber on its no call list, it would later remove the prescriber from its “no-call” list based on a pretense, and resumed calling to drive sales back up.

Purdue undertook these types of actions relative to Tennessee prescribers and pharmacies.

135. Moreover, even in the limited instances when Purdue placed a prescriber on its “no call” list, Purdue often *did not report that prescriber* (or the associated clinic or other clinicians) to the DEA, to state law enforcement, or to state licensing agencies. This ensured that prescribers that *Purdue subjectively had identified as engaging in suspicious practices* could *continue to prescribe OxyContin and other Purdue opioids*. In this fashion, Purdue allowed diversion by the prescriber to continue unless and until some outside event (such as an arrest) made it impossible for that prescriber to keep issuing prescriptions and feeding the illegal drug market. Purdue knowingly continued to stock pharmacies that filled prescriptions for these problematic prescribers. Upon information and belief, Purdue engaged in these practices relative to Tennessee prescribers and pharmacies, including prescribers and pharmacies serving the Counties. Upon information and belief, the Distributor Defendants assisted Purdue in continuing to supply these types of suspect prescribers even after they were placed on no-call status, and the Retailer Defendants continued to fill the associated prescriptions.

136. Through these practices and others, Purdue knowingly facilitated diversion of its products into the Tennessee illegal drug market by pill mill operators whose diversionary activities

Purdue encouraged, including the Prescriber Defendants. Purdue called on these prescribers for years, and often did so until authorities either stripped the prescribers (or practices) of their licenses or the individuals were arrested.

137. To take just a few examples (separate and apart from Purdue's relationship with the Prescriber Defendants), Purdue knowingly established relationships with the following problematic prescribers and knowingly supplied pharmacies with large volumes of opioids to fill their scripts Purdue supplied prescriptions written by all of these prescribers and clinics through the Drug Distributors.

a. Dr. Thomas Esser (Jonesborough and Knox County)

Thomas Esser, a physician's assistant in Jonesborough who worked at Bearden Healthcare in Knoxville, prescribed over 810,358 OxyContin pills between 1998 and 2017, over 75% of which were for 40 mg doses or higher (the most heavily abused dosages). In 2010, Purdue learned that Mr. Esser had lost his pharmacy license. Purdue initially placed him on a no-call list and reported him to the DEA. However, in 2012, Purdue allowed Purdue sales representatives to resume calling on both Esser and, upon information and belief, the clinic employing him.

b. Dr. Allen Foster and Gwendolyn Noe (Multiple Locations):

Dr. Allen Foster operated three pain clinics in Tennessee and prescribed over 1 million tablets of OxyContin between 1998 and 2017, 85% of which were 40mg dosages or more. Purdue learned that Gwendolyn Noe, an individual worked for Dr. Foster, might quit because she thought her licensure would be in jeopardy if she continued to work for him, that he was seeing 60 patients a day, and that she was being chastised "for being too stringent on drug screening for fear of losing the patient." Purdue nevertheless continued to call on Ms. Noe at that same practice. In 2006, Purdue also received a report associating Dr. Foster with a criminal drug ring in Morristown, Tennessee (where two of the clinics were located), but nevertheless continued to call on Dr. Foster's practice. After calling on Dr. Foster for 10 months to push him to sell more opioids, Purdue finally put him on a no-call list and reported him to the DEA. However, in July 2009, ***Purdue resumed calling on Dr. Foster to prescribe more OxyContin***, and he continued to write OxyContin scripts. Purdue placed Dr. Foster on no calling status just 17 days before he plead guilty to health care fraud on February 24, 2011. The guilty plea explained that Dr. Foster had operated a "fast track" system, whereby PAIN patients did not actually see Dr. Foster or any of his licensed medical providers. Instead, Dr. Foster had his clinic prescribe painkillers to pain management patients during monthly visits

without actually having a face to face interaction with a licensed medical provider. Dr. Foster then fraudulently billed Medicare for “visits” with pain patients that never actually occurred. After the guilty plea, Purdue reported Dr. Foster to the DEA. In 2012, Tennessee revoked Dr. Foster’s license to prescribe controlled substances.

Despite all of these issues, and even after reporting Dr. Foster to the DEA, Purdue still continued to call on other practitioners associated with his clinic (including calling on Ms. Noe through 2015).

c. Sherry Barnett and Dr. Dana Brown (Johnson City):

Sherry Barnett was a nurse practitioner who operated a pain management clinic in Johnson City. A Kingsport pharmacist told Purdue that it should stop contacting Ms. Barnett because she was writing prescriptions for short-acting opioids and allowing patients to refill prescriptions early. Although Purdue placed Ms. Barnett on no-call status, it continued to call on her supervising physician, Dana Brown, and a nurse practitioner, Cheri Dickinson, who were operating in Kingston. In 2014, Brown told Purdue that one of the patients was “melting OxyContin down and shooting it up.” Purdue continued to call on Dr. Brown to prescribe more opioids. In August 2014, Ms. Barnett’s clinic shut down due to an investigation by the Tennessee Bureau of Investigation. Purdue still continued to call on Dr. Brown’s clinic. In 2016, Ms. Barnett was criminally charged, and the Tennessee Board of Medical Examiners placed Dr. Brown’s license on probation for five years.

d. Michelle Cate (Bulls Gap):

Cate was a nurse practitioner who operated a practice in Bulls Gap. The practice was not certified as a pain management clinic and, from October 2012 until it closed in December 2013, operated without a supervising physician. Purdue nevertheless called on Cate repeatedly to prescribe more OxyContin, during a time in which the facility was unlicensed and unsupervised. Purdue also continued to call on Ms. Cate to prescribe more opioids despite receiving a report of concern from its sales associate that Cate’s (supposed) supervising physician was located in Colorado and checked patient charts just once a month. During this time frame, Purdue categorized Ms. Cate as a “SuperCore” prescriber for OxyContin and Butrans. In February 2014, Tennessee revoked Cate’s APN certification and placed her license on probation. In 2015, a Hawkins County grand jury issued an indictment against her for unlawfully distributing controlled substances. The local Sheriff characterized her as having operated a “pill mill.”

e. Knoxville Pill Mill Conspirators

Purdue regularly called on a network of East Tennessee clinics and clinicians who were raided by the FBI in March 2015 and charged with a criminal drug

conspiracy. Purdue called on the clinics to prescribe more opioids, despite obvious indications that the calls were facilitating criminal diversion. A woman named Sylvia Hofstetter coordinated this pill mill conspiracy, moving from Florida to Tennessee specifically to open pill mills to supply drugs to addicts and drug dealers for cash. The federal government described Ms. Hofstetter as “the largest drug dealer ever to set foot in the Eastern District of Tennessee. The FBI linked this conspiracy to at least two overdose deaths.

The conspiracy included a multi-office entity named Comprehensive Healthcare Systems (“CHS”) in Lenoir City and Knoxville. Purdue received multiple reports containing obvious signs of diversion by CHS. For example, Purdue learned that a CHS location was located in a sparsely populated strip mall area, in which the parking lot was full of out-of-state license plates. Purdue ascertained that the clinic was filled with younger “patients” in a crowded waiting room, that medical staff were evasive when asked what providers were present, and that a patient had announced “I got it” to two people waiting in a car in the parking lot. Purdue learned this clinic was part of an “organization” with 4 separate offices and 5 providers. Purdue only placed a nurse practitioner at the facility on its no-call list, but continued to call on the rest of the practice and urged them to prescribe more OxyContin, including the other locations. Purdue also learned that other CPS facilities had a parking lot full of state license plates and “young” patients, that an older person was “coaching” a “nervous” younger person how to fill out forms, that there was a “revolving door” of providers, and that local pharmacists had voiced concern about CHS’s prescription practices. CHS also prescribed opioids to thousands of patients in exchange for grossly excessive fees, only accepted cash, and required its “patients” to come for appointments every 28 days. Nevertheless, Purdue continued to call on CHS at multiple locations while they were diverting drugs. Purdue also called on a physician at CHS who was among its top 50 prescribers in Tennessee, but whose license was later revoked. Furthermore, in 2015, Purdue learned that CHS was intentionally bringing “new people into the mix” to issue prescriptions in their names, in order to reduce the average number of prescriptions per prescriber. The FBI raided CHS in March 2015.

Purdue also called an entity within this criminal conspiracy called East Knoxville Health Care Services, urging it prescribe more OxyContin at the same time, that it was engaging in criminal conduct. Like CHS, EKHS dispensed inordinate amounts of opioids in exchange for grossly excessive fees, and accepted only cash. The FBI raided CHS in March 2015. Purdue also called on additional members of the criminal conspiracy to push them to prescribe more OxyContin, including Dr. David Brickhouse and Jamie Cordes, even after learning that the FBI in 2010 had raided a previous clinic in Marvville (Breakthrough Pain Therapy) where they had worked. When Brickhouse and Cordes open a new clinic called “Prodigal Primary Care,” Purdue called on them anyway. Furthermore, Purdue continued to call on them after learning that PPC had a parking lot “full of cars, with many people sitting in them or smoking outside,” including “a person who looked stoned,” with license plates from other counties. In 2014, a Federal grand jury indicted both Cordes and

Brickhouse for illegally prescribing and distributing controlled substances while at Breakthrough Pain. Purdue did not place Cordes or Brickhouse on its “no call list” until after the indictment.

f. Gregory Hines (Lawrenceburg/Lawrence County)

Dr. Hines operated a practice in Lawrenceburg. He was one of Purdue’s highest OxyContin prescribers from 2003 through 2017, including twice as many doses over 40mg than under 40 mg. In 2009, a nurse told Purdue that “she was concerned there may be a drug ring in Lawrenceburg,” that Dr. Hines had prescribed a particular patient 120 pills of 80 mg OxyContin pills three times in 16 days, that the patient had in turn sold some of the pills herself and gave some to Dr. Hines, that the patient had been arrested, and that she was unsure if anything had “happened to Dr. Hines yet.” After reviewing this information, Purdue within a less than week specifically authorized sales representatives to continue calling on Dr. Hines to press him to prescribe OxyContin. Purdue never placed Dr. Hines on a cease calling status and continued to call on him through at least 2017. Dr. Hines is the “Dr. Z” referenced in the complaint filed against Purdue by the Tennessee Attorney General’s Office.

g. Dr. Abdelrahman Mohamed (Morristown):

Dr. Mohamed, based in Morristown, was one of Purdue’s highest prescribing physicians for OxyContin before he plead guilty to health care fraud in federal court in 2017. Between 2006 and 2016, he prescribed 544,202 total tablets of OxyContin. Purdue regularly called on Dr. Mohamed, invited him to programs outside the office, and sent managed market specialists to answer his questions about third-party coverage of Purdue’s opioids. As detailed in a subsequent federal indictment, Dr. Mohamed operated a “drive through” pill mill, whereby his staff lined up scores of patients to whom he issued pre-filled opioid prescriptions after spending just one to two minutes with each person. Even after a doctor told Purdue of “drug abuse and diversion” in the parking lot outside Dr. Mohamed’s practice and that Dr. Mohamed was overprescribing OxyContin. Purdue was also informed that his waiting room was “standing room” and that he was structuring his prescriptions to evade scrutiny by Tennessee authorities. Nevertheless, Purdue continued to call on him and drive him to prescribe more OxyContin. In 2017, Mohamed was arrested and plead guilty to federal felony charges associated with his “drive through” pill mill operation. He is currently incarcerated. Purdue never once placed Mohamed on its no-call list. Mohamed was also a top prescriber of Opana ER whom Endo specifically targeted to prescribe more Opana ER.

h. Dr. McNeil/Bearden (Knox County):

Dr. McNeil operated a pain clinic in Knoxville, TN, named Bearden Healthcare Associates. From 2006 to 2016, Dr. McNeil wrote 15,196 prescriptions for OxyContin (nearly 1.7 million tablets), including 758,478 tablets of OxyContin 80

mg – the highest dosage. Many of Dr. McNeil's patients paid in cash. Between 1998 and 2017, Dr. McNeil prescribed over 3.3 million tablets of OxyContin, approximately 80% of which were 40 mg or higher. The co-owner of Dr. McNeil's clinic prescribed nearly 1.2 million tablets of OxyContin from 1998 to 2017, over 80% of which were 40mg dosages or higher.

In 2003, Purdue received learned that the Tennessee Board of Medical Examiners had disciplined Dr. McNeil for improper prescribing practices, unprofessional and unethical conduct, and prescribing to drug addicts. Purdue placed Dr. McNeil on a no-call list, but continued to call on his co-owner. In November 2006, Purdue interviewed a Knox County Sheriff's Office detective, who told them Dr. McNeil was among the "most problematic physicians being investigated" and that "most prescriptions" coming out of his clinic were for 180 40 mg or 80 mg OxyContin tablets. That detective stated that, of all diversion in the area, 95% was attributable to several "dirty doctors" who were writing "cookie cutter prescriptions" that amounted to "clear diversion" – including Dr. McNeil and his wife (who also worked at Bearden).

Despite being on cease calling status, Purdue sales representatives called on Dr. McNeil 13 times between May 2007 and October 2, 2007 – without penalty by Purdue – and he continued to write OxyContin scripts. In October 2007, Purdue authorized sales associates to begin calling him again (although they had already been doing so). Purdue called on Dr. McNeil and his co-owner over 160 times between May 2007 and February 2011. In August 2008, Purdue learned of an article describing how the Knoxville Police Department and the DEA had identified a single problematic pharmacy that was "just around the corner" from Dr. McNeil's clinics, was the only one filling his prescriptions, and accordingly "dispenses the highest volume of narcotic drugs (oxycontin, hydrocodone, oxycodone) in the State of Tennessee." The report indicated that pharmacy customers were being mugged at gunpoint, that drug deals were taking place in the parking lot, and that neighbors were trying to convince the pharmacy to stop filling Dr. McNeil's scripts. Nevertheless, Purdue continued to detail Dr. McNeil, calling on him over 100 times after receiving this report.

Dr. McNeil's DEA license expired on April 7, 2011. Unable to sell to him anymore, Purdue placed him on cease calling status and finally reported him to the DEA the next day. In March 2018, Tennessee permanently revoked Dr. McNeil's license, finding that, since 2002, he had prescribed opioids in "excessive amounts", "for durations not medically necessary . . . and/or not for a legitimate medical purpose," and "without appropriately monitoring for abuse and diversion."

Furthermore, during this time frame, Purdue continued to call on the other practitioners at Bearden, many of whom were also among the highest volume OxyContin prescribers in Tennessee. In 2011, it received multiple reports from local medical professionals stating that Bearden should be shut down for overprescribing opioids, that the Bearden parking lot was "always full of people

waiting in cars for patients to get their prescriptions, that Bearden practitioners were prescribing “unusually large quantities of opioids.” Purdue continued to call. At least through 2012, Purdue still did not place the clinic as a whole on cease calling status, and even after 2012 continued to call on individual Bearden clinicians through 2014. Purdue resumed calling on Bearden in 2017.

i. Dr. Richard Aballay/Bearden (Rutherford County)

In or about 2013, after Dr. McNeil lost his license, Dr. Aballay became the medical director for Bearden. While serving as Bearden medical director, Dr. Aballay also served as medical director of a pain clinic in Murfreesboro from 2013 to 2015 and another medical practice from 2015 to 2017. Purdue identified his association with Bearden at least as early as September 13, 2013, when a Purdue sales representative sought to determine if he could call on Dr. Aballay. Purdue continued to call on Dr. Aballay at his Murfreesboro office. Purdue received another report expressing concerns regarding Dr. Aballay in May 2014. Purdue continued to call on him. In July 2014, Purdue explicitly authorized sales representatives to continue calling on Dr. Aballay, and he continued to write OxyContin scripts. Purdue did not formally place Dr. Abalay on no calling status under April 2015.

j. Linda Foster (McMinnville/Warren County):

Dr. Foster operated a pain management clinic in McMinnville, Tennessee. Tennessee suspended her medical license on March 18, 2015 after admitting to prescribing Vicodin to six (6) family members and Adderall to her son in 2012 when it was not pursuant to an emergency situation.” The same day that Dr. Foster’s license was suspended, Purdue called on her. It continued to call on her through July 21, 2015, when Tennessee also revoked the state certification for her pain management clinic.⁵⁹ Purdue still called on her the next day. Despite her suspension and the clinic’s de-certification, Dr. Foster illegally continued to supervise mid-level practitioners while her license was on probation.⁶⁰ Purdue nevertheless continued to call on her. On November 15, 2015, Tennessee added two years to Dr. Foster’s suspension for illegally running her pain clinic without certification or a medical license.⁶¹ Purdue *still* continued to call on her. From the date of her initial suspension through 2017, Purdue called on Dr. Foster 70 times, and both she and her nurse practitioner continued to write OxyContin scripts.

k. Summer Keasler (Chapel Hill/Marshall County):

⁵⁹ See Consent Order, *In the Matter of Linda Foster M.D., P.C., Certificate No. 118, et al.*, Complaint No. 2015008401, Commissioner of the Department of Health, July 21, 2015.

⁶⁰ See Consent Order, *In the Matter of Linda A. Foster, M.D.*, Case No. 2015013851, Tennessee Board of Medical Examiners, November 10, 2015.

⁶¹ *Id.*

Summer Keasler was an Advanced Practical Nurse who owned the North Medical Clinic in Chapel Hill, Tennessee, a clinic for which Defendant David Florence served as medical director. Purdue called on Keasler frequently, and Keasler accordingly prescribed 1,002 OxyContin scripts between 2010 and 2013. In August 2012, Purdue placed her on no call status after learning that a local pharmacy would no longer fill her prescriptions for oxycodone because Keasler was prescribing unlawfully. However, upon information and belief, Purdue did not report her to the DEA or to any state or federal law enforcement agencies, and she continued to prescribe OxyContin in large volumes. On June 6, 2013, Tennessee summarily suspended her license and then revoked it on August 20, 2014. The Tennessee Board of Nursing found that Nurse Keasler had engaged in a laundry list of illegal activity, including running her practice while addicted to (and under the influence of) controlled substances, over-prescribing, and failing to maintain her licensure requirements.⁶²

1. Amy Powers (Murfreesboro/Rutherford County):

Amy Powers is an Advanced Practical Registered Nurse practicing in Murfreesboro, Tennessee. Purdue identified her as one its “Top 100” OxyContin prescribers in Tennessee. Indeed, despite writing only a single OxyContin script before 2011, Nurse Powers ranked 50th in the state of Tennessee for total OxyContin prescriptions written from 2006 to 2016, writing 4,065 OxyContin prescriptions from 2011 forward. Purdue called on Powers from 2006 at least through August 2016 (convincing her to begin prescribing OxyContin in 2011). On May 1, 2011, Purdue’s diversion detection program identified a red flag as to Ms. Powers. Purdue continued to call on her to prescribe more OxyContin anyway – before Purdue’s suspicious order monitoring team had even made a decision regarding the report of concern. At any rate, on August 1, 2011, for unspecified reasons, Purdue recommended that sales continue calling on Powers to press her to prescribe more OxyContin. Also, Endo targeted Ms. Powers as a “decile 10 prescriber” for Opana ER (meaning she was among the top 10% of Endo’s customers by volume of Opana ER scripts).

m. Cindy Scott (Cookeville/Rutherford County):

Cindy Scott is an Advance Practical Nurse who has worked for multiple pain treatment centers since 2012, including a pain management facility in Cookeville from 2012 to 2014. Purdue called on Ms. Scott from at least January 2006 to October 4, 2016. From 2006 to 2016, she issued 2,446 scripts for OxyContin, ranking 102nd in Tennessee by OxyContin prescription volume. Furthermore, from April 1, 2012 to December 31, 2014 (during which time she practiced in Rutherford County), she was among the top 50 controlled substances prescribers in Tennessee. In November 2013, Purdue received a report that local pharmacies were refusing to fill Ms. Scott’s prescriptions because of the volume of short-acting opioids she was

⁶² *Id.* at ¶¶ 24-31.

prescribing. Within days, Purdue told sales representatives that they could continue calling on Ms. Scott. Purdue conducted no further investigations regarding Ms. Scott.

On November 29, 2016 (less than 60 days after Purdue had last called on Scott), Tennessee placed Scott's RN license on probation, suspended her RN certificate, required her to surrender her DEA registration, and assessed civil penalties. It found that her prescription practices since 2012 had been non-therapeutic in nature, were "neither justified nor medically necessary for patients' diagnoses, and not for legitimate purpose," and that she had "often prescribed monthly prescriptions to individual patients exceeding a daily dosage of five hundred (500) morphine milligram equivalents which included inappropriate combinations of long and short acting opioids often combined with high amounts of a benzodiazepine and/or carisoprodol."

n. Ambre Maze & The Pain Management Group (Rutherford, Wilson, Davidson, Williamson Counties)

Ambre Maze is a physician's assistant who practiced in multiple counties from 2007 to 2016 at multiple pain management groups, including a pain clinic in Murfreesboro from 2014 forward. Between 2006 and 2016, she ranked 59th in Tennessee for overall OxyContin prescriptions. Purdue detailed her frequently from at least 2007 to 2016 to convince her to prescribe more OxyContin. At one point, she worked for a pain management clinic in Antioch called The Pain Management Group, one of the largest pain clinics in Tennessee. The Pain Management Group had an in-house pharmacy called "Wellness Pharmacy" that wrote a high volume of opioids scripts and that also had a sister pharmacy in Murfreesboro. They worked hand in hand to over-supply the area with high volumes of opioids. Upon information and belief, McKesson was the sole distributor for The Pain Management Group at least through 2013.

In 2010, Purdue specifically examined the Wellness Pharmacy for potential suspicious practices. Purdue learned that it was serving one of the largest pain clinics in Tennessee (*i.e.*, the Pain Management Group where Maze worked), that it was filling scripts for patients from all over Middle Tennessee, and that the pharmacy also filled scripts for other pain clinics. All of these were red flags indicative of diversion by both the Wellness Pharmacy and the Pain Management Group with which it was associated. Despite these obvious issues, Purdue continued to call on Maze and other prescribers at The Pain Management Group to prescribe even more OxyContin – prescriptions that the Wellness Pharmacy continued to fill. Upon information and belief, Purdue also continued to call on The Wellness Pharmacy, and McKesson continued distribute pills to it despite obvious signs of diversion.

In July 2013, Endo and, upon information and belief, Purdue both learned that (a) McKesson had cut off distribution to The Wellness Pharmacy and (b) that the

pharmacy was having difficulty locating *any* distributor to fill its high-volume orders for prescription opioids. Despite these glaring indicia of abuse and diversion by the Wellness Pharmacy and the Pain Management Group with which it was associated, Purdue continued to call on Maze to prescribe even more OxyContin. Purdue continued to urge Ms. Maze to prescribe more OxyContin, after she left the Pain Management Group. In all, Purdue directly urged Maze at least 225 times to prescribe more OxyContin.

138. In all of these examples, Purdue (and, where appropriate, Endo) took actions to encourage pill mills to prescribe more opioids that Purdue knew were being overprescribed and feeding the illegal drug market. These are just examples of specific acts by Purdue that facilitated illegal drug transactions.

139. Upon information and belief, relative to the preceding examples, the Distributor Defendants supplied the vast majority of drugs that filled those prescriptions. Upon information and belief, they knew of the prescribing patterns of these pill mills and knew that the corresponding pharmacy orders were (manifestly) suspicious. Distributor Defendants nevertheless filled those orders despite knowing that they would be diverted. Upon information and belief, the Distributor Defendants engaged in similar actions by filling orders for high-volume prescribers despite red flags. Upon information and belief, Endo and Mallinckrodt detailed these same prescribers to urge them to prescribe their opioids, and the Retailer Defendants filled prescriptions that they wrote.

140. Purdue also called directly on pharmacies making unusual and suspicious orders, and kept doing so even after learning extensive information indicating diversion and clear over-prescribing. As with prescribers, Purdue tracked which pharmacies dispensed the most drugs for Purdue prescribers and treated them as Purdue customers. Purdue called on these pharmacy customers to ensure that they filled OxyContin prescriptions, handled customer rebates, and that Purdue and its distributors kept the shelves sufficiently stocked to supply the outlandish number

of prescriptions that Purdue was procuring through its detailing of prescribers. Purdue did so relative to high-volume pharmacies in Tennessee.

141. For example, Purdue called on Food City in Knoxville for years. Food City filled scripts for Bearden, at one time operating as the exclusive pharmacy for scripts issued by Bearden clinicians who, as discussed above, were plainly over-prescribing and supplying the illegal drug market. Food City had the fifth highest volume of OxyContin sales in the entire country. After receiving reports of concern, Purdue began investigating Food City, but allowed its sales associates to continue to call on the account for years while its investigation was underway. During this investigation, Purdue learned that, among other things, Food City refused to cut off Bearden because it constituted a “revenue stream,” that other pharmacies had all stopped filling Bearden prescriptions, that the company needed an armed security guard, and that some wholesalers had suspended Food City or capped its orders. Purdue nevertheless authorized sales personnel to continue to call on Food City. Furthermore, when Purdue’s risk management team finally recommended that Purdue report Food City to the DEA, *it still authorized representatives to continue calling Food City to stock its shelves with OxyContin.*

142. Purdue also presented a study of OxyContin abuse in rural Kentucky which showed that oral abuse of OxyContin and Oxycodone increased following the introduction of the abuse-resistant drugs. With full knowledge of the diversion risk, Purdue flooded the market without safeguards and ignored evidence of diversion where it was plain. As detailed elsewhere in this Complaint, Purdue further made misrepresentations regarding the properties of opioids, thereby knowingly causing illegal over-prescribing and giving rise to the addicts that require diversion to feed their habits.

143. Purdue further knowingly participated in the illegal drug market in Tennessee and elsewhere promoting the abuse-deterrent properties of OxyContin, by deliberately and knowingly downplaying addiction risks associated with opioids and through the other conduct detailed in this Complaint. Those actions were designed to expand Purdue's market for opioids by inducing the medical community to overprescribe those drugs.

144. By all of these means, Purdue knowingly entered and participated in the illegal drug market in Tennessee and the Counties. Purdue was not a passive participant in the stream of commerce from production to retail sales of its opioids. It created direct relationships with physicians and pharmacies. It actively encouraged physicians to engage in prescription practices that it knew would create opioid addicts (*i.e.*, the illegal market participants). It chose to send sales representatives to convince pill mills and illegitimate prescribers that it knew were feeding the illegal drug market *to prescribe even more pills*.

145. Purdue is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Purdue knowingly participated in the illegal drug market in the Counties by supplying quantities of its products to physicians and pharmacies in the Counties whose prescribing habits necessarily or likely reflected unlawful diversion.

146. Purdue knows that the outlandish prescribing levels in Tennessee and in the Counties necessarily reflect illegal prescribing and diversion of opioids in the aggregate. It also knows of massive diversion based on "pill mills" that it has tracked and identified, notifications from concerned pharmacies within Tennessee, and publicly available information including publicized opioid-related criminal prosecutions.

147. In recent years, Purdue has finally at least acknowledged that opioid addiction and abuse are a problem, although it continues to supply the illegal drug market. In a presentation

before the Governor's Working Group on or about September 11, 2015, Purdue conceded that "[t]he abuse of prescription opioid analgesics in the US is a significant public health problem," conceded that "OxyContin ... is subject to misuse, addiction, and criminal diversion," and conceded that even after the creation of abuse-resistant OxyContin, "abuse by these routes [injection and nasal], as well as the oral route, is still possible."

148. Despite widespread abuse, addiction, and diversion, OxyContin remained the most frequently prescribed branded opioid throughout Tennessee from September 2015 through August 2017.⁶³ Although Purdue recently has paid lip service to the related issues of opioid abuse and diversion, it has not undertaken any effective measures to stem the flow of opioids destined to create more addicts and to be sold in illegal drug markets. It could take such measures, but refrains from doing so in order to profit from opioid abuse and diversion. It is a knowing participant in the continuing "ring of abuse."

iv. Richard Sackler Knowingly Participated in the Illegal Drug Market in Tennessee by Directing Purdue Repeatedly to Distribute Drugs Unlawfully and Otherwise to Facilitate Diversion

149. The Sackler family knowingly participated in the illegal drug market in Tennessee.

150. The Sackler family owns Purdue (which is a private company) and has always held a majority of seats on its board. By virtue of their control, they have had the power to (and in fact did) dictate how addictive narcotics were sold in Tennessee and elsewhere. They hired workers who helped them facilitate the creation of addicts and diversion of Purdue opioids. They fired workers whom they believed did not sell enough drugs. They controlled, ratified, and otherwise directed Purdue to commit the misconduct described in this complaint. For example, they pushed Purdue and its employees to hook more patients on opioids at increasingly higher dosages, paid

⁶³ QuintilesIMS Data.

themselves billions of dollars, and are also responsible for the injuries sustained by Baby Doe in the Counties.

151. Richard Sackler is the one of three brothers who founded Purdue Frederick Company in 1952. Since that time, Richard Sackler has had a controlling interest in Purdue (including the affiliated companies Purdue Pharma Inc. and Purdue Pharma L.P. that he founded with other Sackler family members in 1990).

152. Richard Sackler took a personal interest in pushing Purdue and its employees to commit the misconduct alleged elsewhere in this complaint.

153. Richard Sackler resigned his position on Purdue's Board in 2007. However, he personally and informally continued to exert control over Purdue's operations, including personally directing Purdue employees to drive sales in Tennessee, to contact the highest volume-most dangerous Tennessee prescribers to urge them to prescribe more OxyContin, and otherwise to push pills into Tennessee communities despite knowing that it was causing widespread addiction, abuse, diversion, injury, and overdose deaths.

154. From the outset of OxyContin's launch forward, Richard Sackler pushed Purdue to market and promote OxyContin increasing volumes, regardless of the consequences and regardless of what he and Purdue actually knew about the risks and dangers of the product. At the OxyContin launch party, he announced that "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white"

155. In connection with OxyContin's launch in the US, Richard Sackler advocated for Purdue simultaneously to push OxyContin pills into foreign markets as a uncontrolled substance without safeguards that protect patients from addictive drugs. When a Purdue official expressed

concern that this would cause the drug to be abused, Richard Sackler responded by asking how substantially this would affect Purdue's sales.

156. Richard Sackler's sole interest was driving sales to line his pockets and those of family members. For example, when he learned in April 1997 of OxyContin's initial success, he responded "Spectacular sales. Congratulations to all. OxyContin tablets are now at a run rate that makes it bigger than either the U.K. or Germany[,]", and "Harrah. All hail the new state of OxyContin tablets."⁶⁴ Similarly, after learning of daily sales figure in November 1997, he stated: "I can't believe these bookings and these billings. Fantastic. Let's see, \$10mill a day times 240 days..."⁶⁵

157. In 1999, Richard Sackler became the CEO of Purdue.

158. In 2001, after receiving reports of widespread abuse and overdose deaths from OxyContin, Richard Sackler determined that Purdue should seek to shift blame onto opioids addicts and stigmatize them for their plight.

159. Richard Sackler voted to enter into Purdue's 2007 federal plea, the associated corporate integrity agreement, and the 2007 Tennessee settlement.

160. Richard Sackler was personally involved in pushing Purdue to engage in misconduct, including misconduct in Tennessee. This included directing Purdue to promote OxyContin in a manner that he knew would result (and had resulted) in staggering rates of addiction, abuse, and diversion.

161. Richard Sackler knowingly sent sales representatives into Tennessee to promote opioids to Tennessee prescribers thousands of times, knowingly directed those sales

⁶⁴ PPLPC008000001131.

⁶⁵ PPLPC008000001956.

representatives to target the highest volume prescribers – including pill mills – to prescribe even more opioids. He knew and intended for Purdue to target the prescribers who were engaging in diversion and who were otherwise engaging in rampant over-prescription of opioids. He knew that, by doing so, he was essentially directing Purdue to create addicts and fuel the illegal drug market by blanketing Tennessee (and small, rural communities within it) with OxyContin and other opioids. But he did not care, so long as sales volume remained high.

162. Richard Sackler micromanaged sales operations for Purdue, including efforts directed at Tennessee prescribers. These included:

- Demanding that sales and marketing brief him on how “opioids savings cards” would drive sales, which Purdue utilized for that purpose in Tennessee and elsewhere.
- Demanding immediate and frequent reports regarding sales strategies, and forcing the sales team to change its strategies when he found the sales targets to be too low for his liking.
- Demanding that Purdue’s sales and marketing team pursue new or different strategies to drive sales.
- Telling the sales team that he would be able to influence the Board’s decisions regarding sales and marketing strategies for OxyContin that Purdue utilized in Tennessee and elsewhere, and in fact exerting such influence.
- Convincing the Board to expand the sales force to allow them to push OxyContin more frequently and aggressively to the highest-volume prescribers, including those in Tennessee.
- Demanding weekly reports concerning OxyContin sales and demanding other forms of customized reports, including reports reflecting sales in Tennessee.
- Demanding that sales representatives visit 7 or more prescribers per day in Tennessee and elsewhere.
- Encouraging the sales force to place representatives whose sales were not high enough to be placed on performance improvement plans to drive sales back up.
- Influencing Purdue to set high quotes for the number of visits that the sales force needed to make each quarter, often over 100,000 times per quarter, including thousands of visits

on Tennessee prescribers.

- Criticizing Purdue's sales force for targeting "non-high potential prescribers" rather than the highest volume prescribers.
- Demanding that he be allowed to shadow sales representatives in the field to evaluate their performance, and in fact joining sales representatives in the field to promote opioids.
- Requiring Purdue's sales to identify "corrective actions" to be taken when sales did not meet his desired targets.
- Devising strategies to avoid scrutiny by law enforcement and governmental scrutiny.

163. In April 2008, in an effort to avoid liability, Richard Sackler recommended that it was important to install a new CEO who would remain loyal to the family. He expressed that Purdue's business posed a "dangerous concentration of risk" and that it was vital to have loyal subordinates in place to provide a legal shield. According to him, "People who shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint." Richard also proposed that the Purdue either sell the company or, in the alternative, milk profits from the business and "distribute more free cash flow" to themselves.

164. Richard Sackler knew and intended that Purdue sales representatives in Tennessee spread misinformation concerning opioids and encourage prescribing practices that they knew would result addiction, abuse, and diversion on a wide scale. These practices included:

- a. Hiring personnel to assist Purdue in pushing pills on prescribers and patients to get them addicted to OxyContin through long-term use for chronic pain.
- b. Threatening to have Purdue fire employees who did not meet Richard's demands.
- c. Attempting to foist blame onto patients that Purdue had convinced prescribers to hook onto its drugs.
- d. Pushing opioids for elderly patients without disclosing the higher risks.
- e. Pushing opioids for patients who had never taken them before, without disclosing the higher risks.

- f. Pushing opioids as substitutes for safer medications based on improper comparative claims.
- g. Pushing the notion of “pseudoaddiction.”
- h. Encouraging Purdue to promote OxyContin as non-addictive except as to individuals with a prior history of drug abuse.
- i. Driving sales personnel to push pills on the most dangerous and/or corrupt prescribers, and reprimanding sales personnel for taking any actions that did not drive sales higher.
- j. Encouraging Purdue to fill suspicious orders without investigation.
- k. Preventing Purdue officials from taking any actions that might decrease sales, such as implementing a legitimate suspicious order monitoring program.

165. Richard Sackler also directed Purdue to pay top prescribers money to encourage other prescribers to engage in dangerous practices in Tennessee that he knew would create addicts and foster diversion in Tennessee.

166. Richard Sackler’s micro-management of sales and promotional efforts after 2007 caused Purdue’s CEO to complain about Richard’s “never-ending” requests.

167. Richard Sackler paid himself large amounts of money that they he knew was derived from Purdue’s efforts to push pills onto the most dangerous prescribers and to profit from drug addiction and pill seeking behavior that they knowingly fostered.

v. Mallinckrodt’s Business Model Is Designed to Facilitate Diversion

- 1. Mallinckrodt Has a Substantial Share of the opioid Market in Tennessee

168. After helping to create the opioid epidemic, Mallinckrodt also has worked to sustain that illegal opioids market and to continue profiting from it, including flooding Tennessee with opioids.

169. Mallinckrodt controlled a substantial portion of the opioid market both nationwide and in the Opioid Epidemic Affected Counties during the last several years. Between calendar years 2012 and 2015, based on IMS Health data, Mallinckrodt claimed to enjoy between twenty-three percent (23%) and thirty percent (30%) of DEA Schedules II and III opioid oral and solid doses.⁶⁶ Furthermore, Mallinckrodt saw its sales of Hydrocodone (API) and hydrocodone-containing tablets balloon on average over sixty-three percent (63%) from 2014 through 2016.⁶⁷ During the relevant period of 2012 through 2016, net sales for Mallinckrodt's hydrocodone products were over \$683 million, while net sales of its oxycodone (API) and oxycodone-containing tablets were over \$719 million.

170. For the 24-month period of September 2015 through August 2017 IMS data shows that Mallinckrodt's market share of popular branded and generic opioid products containing hydromorphone and hydrocodone in the State of Tennessee averaged over fifty-five percent (55.4%) and just under twenty-nine percent (28.8%) respectively. Additionally, Mallinckrodt's average market share of oxycodone opioid products in Tennessee was nearly thirteen percent (12.7%).

171. Mallinckrodt made a name for itself on the black market as well. Its blue 30-mg oxycodone tablets became so popular among drug addicts and illegal drug dealers that, at least by 2010, they acquired a street name, "M's," for the company's distinctive block-letter logo.⁶⁸ The pills were also known on the street as "blues" because of their blue color.

⁶⁶ See Mallinckrodt FY2013 and FY2016 10-Ks.

⁶⁷ Mallinckrodt FY2016 10-K (reflecting net sales for Hydrocodone (API) and hydrocodone-containing tablets as for 2014-2016 as \$99.4 million, \$167.2 million, and \$146.5 million, respectively).

⁶⁸ Larry Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, The Washington Post (April 2, 2017). Available at: <https://www.washingtonpost.com/graphics/investigations/dea->

172. In 2011, the DEA began investigating Mallinckrodt, one of the nation's largest producers of generic oxycodone. As a Washington Post article explained, "[i]t was the first time the DEA had targeted a manufacturer of opioids for alleged violations of laws designed to prevent diversion of legal narcotics to the black market. It would become the largest prescription-drug case the agency has pursued."⁶⁹ Relying on confidential government records and emails, the article further explained that the DEA and federal prosecutors had evidence Mallinckrodt "ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012 – 66 percent of all oxycodone sold in the state," and that "the company's lack of due diligence could have resulted in nearly 44,000 federal violations and exposed it to \$2.3 billion in fines."⁷⁰

173. The Washington Post article further explained that, according to an internal summary of the case prepared by federal prosecutors, Mallinckrodt "knew what was going on in Florida," but the company felt it had no duty to even report, or for that matter prevent, the widespread abuse and diversion.⁷¹

2. Mallinckrodt Supplied the Illegal Drug Market in Tennessee Through the "Oxy Express" and a Series of Florida Pill Mills

174. Mallinckrodt knew that multiple Florida distributors, including Sunrise, KeySource, Masters Pharmaceutical, and Harvard were distributing Mallinckrodt products to pill mill operations in Florida that supplied the Tennessee illegal drug market. Even after receiving direct reports of likely diversion by the pharmacies that these distributors were supplying,

mallinckrodt/?utm_term=.8f3c4d303191. [hereinafter "Bernstein, *The government's struggle*"]

⁶⁹ Bernstein, *The government's struggle*.

⁷⁰ *Id.*

⁷¹ *Id.*

Mallinckrodt continued to ship its opioids to those pharmacies in outlandish volumes. Mallinckrodt did business with these entities – and knowingly supplied the Tennessee illegal drug market – until their distribution licenses were revoked. For this reason, the DEA told Mallinckrodt that it viewed Mallinckrodt as the “kingpin within a drug cartel.”

175. Mallinckrodt was aware that Florida pills mills were actively supplying the Tennessee drug market. Highway I-75 runs from Florida through the upper south, including Tennessee. The criminal diversion of prescription opioids along I-75 from Florida northward became known as the “Oxy Express” or the “Blue Highway” (because Mallinckrodt’s oxycodone tablets were blue). Many of Mallinckrodt’s top prescribing pharmacies in East Tennessee were located within a short distance of the Oxy Express, in areas ravaged by the associated illegal drug market.

176. The Washington Post article highlighted Tennessee’s connection to the DEA’s investigation into the diversion of Mallinckrodt’s opioids. As the article explained:

The first hint that Mallinckrodt might pose a problem for the DEA came *not from Florida but from Tennessee*. On July 7, 2009, members of a Tennessee drug task force in a sting operation seized several 100-tablet bottles of Mallinckrodt-made oxycodone. Task force agents alerted Mallinckrodt. The company’s lot numbers were printed on the labels, allowing for easy tracking of the pills. Three days later, Mallinckrodt responded that the oxycodone had been prescribed by Barry Schultz, a doctor who ran a medical clinic in Delray Beach, Fla. The company said that one of its distributors, Sunrise Wholesale of Broward County, Fla., had sent 20,400 tablets of oxycodone to Schultz in the previous year.⁷²

177. According to the Washington Post article, at approximately the same time the Tennessee sting operation was occurring, the Florida Department of Health “issued an administrative complaint against Schultz for prescribing oxycodone outside ‘the course of his

⁷² *Id.*

professional practice.”⁷³ Records showed that Schultz’s “medical office had become a thoroughfare for those seeking easy access to drugs.”⁷⁴

178. In July 2009, a Tennessee law enforcement official in Morristown told Mallinckrodt that pills prescribed by Dr. Schultz in Florida were reaching Tennessee’s illegal drug market and that Dr. Schultz was likely engaging in diversion. Nevertheless, Mallinckrodt did not investigate Dr. Schultz, never talked to Sunrise about Dr. Schultz, and shipped large volumes of opioids to Dr. Schultz *25 times* after receiving the July 2009 report.

179. Mallinckrodt took actions to ensure that Sunrise and Dr. Schultz would feed a pipeline to the illegal drug market in Tennessee. When Mallinckrodt first supplied Sunrise, the company was new and small, had a Yahoo! Email address, and operated a minimalist website. With its first order, Sunrise ordered 2,250 bottles of Oxy 30, which was the most widely abused and diverted Mallinckrodt prescription opioid at the time. Mallinckrodt’s automated system flagged the order. Mallinckrodt asked the national account manager for Sunrise to provide an explanation. Mallinckrodt knew that the national account manager had a financial incentive to justify the order, had an inherent conflict of interest, and therefore should not be consulted or relied upon in determining whether to authorize the order. Indeed, Mallinckrodt specifically received a report internally that this account manager would say anything to make a deal go through. Not surprisingly, the national account manager then provided a transparently inaccurate and insufficient justification for the order. Despite knowing of the conflict of interest and receiving a specific internal warning against relying on that account manager, Mallinckrodt nevertheless accepted the explanation, conducted no further investigation, and shipped the order. To make

⁷³ *Id.*

⁷⁴ *Id.*

matters worse, Mallinckrodt not only filled that suspicious order, it filled additional suspicious orders from Sunrise even after they rose in volume to 15,000 bottles per month without any legitimate reason for that dramatic increase. Mallinckrodt also learned that pharmacies supplied by Sunrise were dispensing prescriptions for practitioners who issued prescriptions based solely on online questionnaires and who were offering controlled substances without a prescription. Even after the DEA even told Mallinckrodt to audit Sunrise to determine whether Mallinckrodt's pills were being diverted, Mallinckrodt *still* continued to ship the suspicious orders from Sunrise. Over a three-year span, Mallinckrodt shipped **49 million pills** through this one distributor alone. Mallinckrodt knew that these drugs were being diverted and knew that they supplying the Tennessee illegal drug market.

180. Sunrise Wholesale and Schultz were not the only ones to draw close scrutiny from the DEA. Another distributor that caught the DEA's attention for sending Mallinckrodt oxycodone to Florida was KeySource Medical, a regional company based in Cincinnati.⁷⁵ In 2010, KeySource Medical sent 41 million tablets of Mallinckrodt-made oxycodone to Florida – enough to supply every person in the state with 2.5 pills.⁷⁶ Additionally, KeySource was a primary distributor to Tru-Valu Drugs in Lake Worth, Florida, which reportedly had “long lines of drug users” and “unorthodox security measures.”⁷⁷ Tru-Valu ultimately became the focus of a 2010 DEA investigation into how prescription painkillers, including Mallinckrodt's opioids, were reaching the black market.⁷⁸

181. In November 2011, the DEA was still pursuing its case against Mallinckrodt and

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

“served a subpoena on Mallinckrodt, demanding documents related to its suspicious-order-monitoring program.”⁷⁹ Through the subpoena, “[t]he DEA gained access to data from Mallinckrodt’s rebate or ‘chargeback’ program,” which, along with other internal Mallinckrodt records, “showed where Mallinckrodt’s oxycodone was going – from the company to its network of distributors to retailers down the chain.”⁸⁰

182. The subpoenaed information, including Mallinckrodt’s “chargeback” data, brought the significance of the 2009 Tennessee drug task force sting operation into clear focus.⁸¹

As the Washington Post article explained:

The DEA learned that in the six weeks after the Tennessee task force alerted Mallinckrodt to the drugs found in the 2009 sting operation, the company had shipped another 2.1 million tablets of oxycodone to Sunrise, the Florida distributor. The DEA also discovered that Sunrise, over an 11-month period, had sent at least **92,400 tablets** to Schultz, the Delray Beach doctor who prescribed the pills found in Tennessee. In one day, he had prescribed **1,000 tablets** to one patient.⁸²

183. At the time, the street value of oxycodone was \$30 a tablet. The Mallinckrodt drugs that Sunrise sent to Schultz (after Mallinckrodt was notified of the Tennessee sting) were worth nearly \$2.8 million on the street, prosecutors said.⁸³

184. In an internal document sent to Mallinckrodt, the DEA expressly stated that “Mallinckrodt knew through law enforcement reports that Barry Schultz was diverting controlled substances, and that the diverted oxycodone was supplied by Mallinckrodt through Sunrise.”⁸⁴ Of particular note, the DEA further stated that: “When Mallinckrodt continued to distribute

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.* (emphasis added).

⁸³ *Id.*

⁸⁴ *Id.*

oxycodone to Sunrise for such purposes, and continued to pay incentives in the form of chargebacks for the product sales to Barry Schultz, **Mallinckrodt was diverting oxycodone.**⁸⁵

In other words, the DEA concluded that, when Mallinckrodt distributed oxycodone that it recognized was being (and would continue to be) diverted, Mallinckrodt was participating in criminal diversion of those drugs.

185. In July 2017, Mallinckrodt agreed to a settlement of \$35 million with the DEA to resolve all allegations of criminal wrongdoing.⁸⁶ In a section titled “Background,” the settlement agreement stated that:

From January 1, 2008, through September 30, 2011, there was an epidemic increase in diversion of the controlled substance oxycodone, largely out of the state of Florida. [¶] The United States alleges that Mallinckrodt, a manufacturer and distributor of oxycodone, knew about the diversion and sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that would result in diversion. . . . [¶] The United States alleges that even though Mallinckrodt knew of the pattern of excessive sales of its oxycodone feeding massive diversion, it continued to incentivize and supply these suspicious sales.⁸⁷

186. As part of the settlement, Mallinckrodt admitted that, with respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt:

- failed to maintain effective controls against diversion;
- “[failed to] conduct adequate due diligence of its customers”;
- “[failed to] detect and report to the DEA orders of unusual size and frequency”;

⁸⁵ *Id.* (emphasis added).

⁸⁶ Administrative Memorandum of Agreement between U.S. Department of Justice, Drug Enforcement Administration and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (“Mallinckrodt MOA”) at 9.

⁸⁷ *Id.*

- “[failed to] detect and report to the DEA orders deviating substantially from normal patterns”; and
- “[failed to] take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream.”⁸⁸

187. Mallinckrodt agreed to take the following prospective ameliorative steps, on top of its \$35 million settlement payment:

- “[d]esign and operate a system that meets the requirements of 21 CFR 1301.74(b)”;
- design of a new suspicious order system;
- prospectively “notify the DEA of any diversion and/or suspicious circumstances”;
- maintain training, security, drug testing, and record keeping policies for its Hobart facility;
- issue record keeping policies consistent with DEA regulations; and
- set a quota for 2017 production that would not exceed its 2015 oxycodone production without DEA consent.⁸⁹

3. Mallinckrodt’s Business Model Was Unlawful and Otherwise Designed to Foster Diversion

188. As with the other defendants, Mallinckrodt’s business model was designed to facilitate downstream diversion of its products.

189. Mallinckrodt had no obligation to fill suspicious orders submitted to it by distributors. It also recognized that it had a responsibility not to fill any potentially suspicious orders without first conducting an independent investigation to clear the suspicion. Thus, each

⁸⁸ *Id.* at 2-3.

⁸⁹ *Id.* at 4-8.

time that Mallinckrodt ascertained (or plainly should have known) that a particular order might be supplying a pill mill or otherwise was suspicious, it had a choice: (1) refuse to ship the drugs (thereby keeping them out of the illegal drug market) or (2) fill the order (thereby supplying the illegal drug market). It chose to ship those orders and knowingly supply the illegal drug market.

190. Mallinckrodt also entered into a contractual relationship with distributors for “chargebacks,” whereby Mallinckrodt allowed distributors to pass through any negative differential between the cost of purchasing the product from Mallinckrodt and the price charged by the pharmacy. In return, the distributors provided Mallinckrodt with sales information that gave Mallinckrodt detailed data concerning where its pills were going and in what amounts, down to the pharmacy or other retailer.

191. Through its chargeback system, Mallinckrodt had control over where distributors shipped Mallinckrodt products. When Mallinckrodt ascertained that a particular pharmacy was potentially operating as a pill mill or had made a suspicious order, it could place the entity on a “no chargeback” list.

192. Functionally, when Mallinckrodt denied chargebacks relative to a particular pharmacy or retailer that a particular distributor supplied, the distributor ceased placing orders with Mallinckrodt relative to that pharmacy. By the same token, by taking a pharmacy off of a chargeback restriction list, Mallinckrodt could re-open the flow of pills. In other words, the chargeback system provided a means by which Mallinckrodt controlled where its pills were going.

193. Accordingly, Mallinckrodt ascertained that particular orders or particular pharmacies were suspicious, it had a choice whether to place that order on a no-chargeback list (preventing the pills from entering a suspected diversion channel) or to proceed with filling orders for that account (allowing the pills to reach a diversion channel). Mallinckrodt consistently chose

to do the latter.

194. As with other defendants, Mallinckrodt's sole goal was driving sales. Mallinckrodt compensated its sales force based on volume. On the branded side, it provided volume-based compensation to its representatives. As with the other defendants, Mallinckrodt knew that sales drive prescriptions.

195. Mallinckrodt intentionally directed its branded sales efforts at the highest volume prescribers of extended release opioids, in particular targeting prescribers in pain management, such as defendant Mark Murphy.

196. Mallinckrodt recognized that these types of prescribers presented an automatic risk and a special danger of operating a pill mill. Mallinckrodt also subjectively knew that by having its sales force target these high-volume prescribers of long-acting opioids, particularly pain clinics, it was targeting entities that were at least as likely to be pill mills as legitimate businesses.

197. Mallinckrodt also knew that absent thorough advance due diligence of these clinics and clinicians (which Mallinckrodt did not undertake), it had no way of knowing whether a high-volume prescriber targeted by its sales was actually a legitimate operation or a pill mill. Nevertheless, it called on these prescribers without conducting due diligence and without determining that the prescriber was not in fact running a pill mill. The incentive was simply to convince prescribers to prescribe as many opioids as possible – with the added benefit that any scripts written for a generic might be filled with a Mallinckrodt generic opioid.

198. Mallinckrodt called on prescribers directly, including Tennessee prescribers, to convince them to prescribe more Mallinckrodt opioids. It therefore established direct relationships with Tennessee prescribers and urged them to prescribe more opioids. Through these efforts, Mallinckrodt not only pushed its branded opioid products on prescribers, but also promoted the

Mallinckrodt name.

199. Also, through direct sales efforts, Mallinckrodt learned detailed information about the prescribing habits of particular prescribers, including Tennessee prescribers. Thus, Mallinckrodt knew which prescribers were likely over-prescribing Mallinckrodt opioids and knew the local pharmacies at which the prescriptions were filled.

200. Just like the other producers, Mallinckrodt categorized its prescribers by sales volume – not as a means to cease filling suspicious orders or calling on suspect prescribers, but rather as a means to drive sales. For example, Mallinckrodt created a list of “three-star” prescribers, reflecting the prescribers most willing to prescribe long-acting and short acting brand opioids. These included Tennessee prescribers in the Counties, as well as other Tennessee prescribers with a sordid history, including Dr. Mohamed in Morristown. Mallinckrodt accordingly promoted its branded products Xartemis and Exalgo to the three-star prescribers and called on those prescribers frequently.

201. Mallinckrodt knew that sales of opioids in Tennessee were particularly high, that Tennessee hydrocodone and oxycodone sales in Tennessee were among the highest in the country, that Tennessee doctors had been arrested for over-prescription practices, and that pharmacies in Tennessee had filled improper oxycodone prescriptions. Nevertheless, Mallinckrodt made Tennessee a top sales target and promoted its products in Tennessee in the same way as it did everywhere else.

202. On the generic side of its business, Mallinckrodt similarly provided volume-based compensation for National Account Managers responsible for maintaining relationships with distributors. This incentivized those NAMs to target distributors who promised the highest volume and/or distributors who supplied pharmacies that plainly serviced pill mills, including the

Distributor Defendants. It also incentivized NAMs to collaborate with distributors, including the Distributor Defendants, to minimize detection and reporting of suspect pharmacies and suspect orders so as not to impact their sales volumes. Mallinckrodt sales personnel also encouraged distributors to market to pain clinics and high volume prescribers, who are sources of diversion. Mallinckrodt promised to meet the increased demand from such efforts.

203. Mallinckrodt subjectively recognized that it had a responsibility to conduct an independent analysis of suspicious orders before completing a sale, so as to determine whether or not those substances were likely to be diverted. It also recognized that it had a responsibility to review orders to determine if they were filling pill mill prescriptions or suspicious pharmacies and, accordingly, to deny chargebacks relative to those dispensing entities until it established the legitimacy of those orders.

204. Despite this recognition, Mallinckrodt coupled its perverse sales incentives with a sham suspicious order monitoring program that was designed to fail, so as to permit downstream diversion to proceed unimpeded.

205. In 2007, the DEA told Mallinckrodt that it should not fill any peculiar orders without first determining that the order not being diverted into illegal channels. The DEA and other industry groups also told Mallinckrodt that it was imperative that Mallinckrodt assess its distributors' customer (such as pharmacies and dispensing physicians) to assess whether Mallinckrodt's pills were being diverted downstream. To that point, Mallinckrodt routinely had filled orders for its distributors without vetting the orders and without ascertaining that the distributors had any suspicious order monitoring programs in place in the first place, let alone programs that were adequate. The DEA also told Mallinckrodt that it should not rely on rigid mathematical formulas to detect suspicious orders.

206. Mallinckrodt did just the opposite. Contradicting specific guidance from multiple sources, including the DEA, Mallinckrodt continued to use a mathematical formula to identify “peculiar orders,” but *shipped those orders anyway*. Mallinckrodt filled those flagged orders without conducting an investigation, without completing an investigation, and/or even where no one responsible for the account could explain why the orders had been placed.

207. Mallinckrodt knew that by filling a flagged order without investigating or completing its investigation, it was likely filling orders that should have been designated as “suspicious,” never filled, and reported to the DEA. Mallinckrodt knew that this practice was completely inappropriate and likely to result in abuse and diversion, but did it anyway.

208. Mallinckrodt also actively avoided taking any measures that would actually have prevented it from filling suspicious orders, from continuing to over-supply Tennessee with opioids, and from feeding the illegal drug market. For example:

- a. Despite producing and shipping prodigious amounts of pills across the country, Mallinckrodt purposely understaffed its controlled substance compliance department, which had only four to eight employees at all times.
- b. It purposely appointed a person to head its suspicious order monitoring committee and design its order monitoring program who was manifestly unqualified. Specifically, it appointed a former typist with a high school education and no formal professional qualifications or training for those roles.
- c. Despite knowing that the reports contained important information, Mallinckrodt screened off adverse event reports reflecting abuse from its SOM committee, which did not even consider them when evaluating the legitimacy of a particular pharmacy. Mallinckrodt did so to minimize the likelihood that any high-volume customers (or particular orders) would be cut off or impounded for engaging in suspicious and dangerous practices.
- d. When Mallinckrodt was reforming its SOM program at the DEA’s behest, it learned that a third-party vendor called Integrichain could use IMS Health Data, ARCOS data from the DEA, and other sources to identify diversion throughout Mallinckrodt’s supply chain. Mallinckrodt recognized that utilizing Integrichain would have prevented Mallinckrodt from continuing to fill suspicious orders and continuing to supply high-volume pharmacies (such as the Retailer Defendants

here) that were over-supplying Tennessee communities. Mallinckrodt did not want to take any action that might actually reduce sales to its largest customers, regardless of whether those customers were feeding the illegal drug market and filling pill mill prescriptions. Accordingly, Mallinckrodt elected not to use Integrichain, and chose instead to utilize its own in-house sham SOM operation that (as described elsewhere herein) it structured to fail.

- e. Relative to Tennessee, Mallinckrodt's SOM committee focused its consideration primarily (and in many instances exclusively) on sources with a conflict of interest, and actively avoided reviewing information that would have hampered sales by cutting off suspicious orders. Mallinckrodt relied on National Account Managers, the distributors themselves, and others with a financial interest in the outcome to clear orders that Mallinckrodt would then ship. By the same token, Mallinckrodt purposely avoided monitoring Tennessee news articles, social media, third-party data, disciplinary actions against prescribers or pharmacies, or IMS Health that made plain which distributors and/or pharmacies were submitting suspicious orders and otherwise engaging in suspicious practices.
- f. Mallinckrodt knew of the existence of pill mills in Tennessee, of which it internally kept a list. However, despite knowing about these pill mills, it adopted a policy *not* to investigate them.
- g. Mallinckrodt's SOM team never once discussed possible red flags for diversion in Tennessee.

209. Furthermore, as with other companies, Mallinckrodt inappropriately placed the primary role for reporting suspicious orders and suspicious prescribers with its sales force. It rewarded sales personnel with sales-based bonuses and encouraged its sales personnel to target the highest volume prescribers to prescribe even more opioids (on the branded side) and to distribute its drugs to the highest-volume pharmacies and dispensing clinics (on the generic side). At the same time, Mallinckrodt did not develop any programs to incentivize sales personnel to locate and report suspicious orders. Thus, a sales person at Mallinckrodt who reported suspicious orders or other suspicious practices by distributors or retailers would have to do so *against* his or own financial interest. Upon information and belief, Mallinckrodt never once penalized a salesperson for calling on and driving sales with a prescriber who unlawfully prescribed Mallinckrodt opioids, nor did Mallinckrodt punish any generic sales personnel for driving sales to a distributor that later

got in trouble for suspicious activity. This ensured that sales representatives would not report suspicious activity and would suffer no consequences for over-supplying Tennessee communities.

210. Similarly, Mallinckrodt knew that sales personnel should have played no role in screening new customers because of their inherent conflict of interest. Nevertheless, Mallinckrodt allowed its sales personnel to bring on new customers without screening by anyone outside the sales force.

211. At the DEA's behest, Mallinckrodt also began issuing questionnaires to its distributors, including AmerisourceBergen, Cardinal, and McKesson, asking for information concerning the pharmacies supplied through those entities. Ostensibly, Mallinckrodt would utilize this information to determine which pharmacies were dispensing pills that reached the illegal drug market. However, contradicting specific guidance from the DEA and industry groups, Mallinckrodt soon stopped requiring these forms and shipped product even where distributors (including one or more of the Distributor Defendants here) did not fill them out. Mallinckrodt also shipped orders where distributors only partially filled out the forms, omitted answers to key questions indicate of potential diversion, or otherwise provided information indicating that a downstream pharmacy or prescribing physician was engaging in diversion (which both Mallinckrodt and the distributor ignored).

212. In addition to disincentivizing reporting, Mallinckrodt also came up with other ways to avoid flagging suspicious orders. For example, despite DEA instructions, Mallinckrodt for years used only a rigid mathematical formula to supplement any reporting that its sales associates would have made (against their own financial interest). The formula was absurd and designed to minimize flagging of suspicious orders: Mallinckrodt only flagged orders where the order was [REDACTED]. Thus, if a distributor

had been submitted absurdly large orders with great frequency in the past – which were inherently suspicious and indicative of diversion – Mallinckrodt would not flag those orders unless and until the size of those orders [REDACTED].

213. Even under this improper metric, Mallinckrodt's SOM team eventually *raised* the threshold [REDACTED] because the list of flagged orders was just too large to process. In other words, so many of Mallinckrodt's customers were making orders [REDACTED] [REDACTED] that Mallinckrodt's SOM team could not keep up. Without legitimate justification, Mallinckrodt changed the threshold for the sole purpose of reducing the number of flagged orders. There was no reason for this other than to reduce oversight and allow diversion to continue.

214. Moreover, even where Mallinckrodt's suspicious order monitoring group received a report of suspicious activity, it found many ways to continue streaming its drugs into diversion channels. For example:

- a. Without verifying whether it was true, the committee would accept wholesale any pretense for a suspicious order offered by the distributor. This occurred even where Mallinckrodt readily recognized (or easily could have ascertained) that the justification was false, misleading, or insufficient. So long as a distributor (including Distributor Defendants) articulated a justification, Mallinckrodt would accept it to "clear" and ship the order.
- b. It cleared and shipped flagged orders without conducting any investigation.
- c. Even in those few instances when it conducted an investigation, it slow-walked the investigation while continuing to ship orders from the flagged entity.
- d. Mallinckrodt knew that sales representatives had a conflict of interest concerning flagged orders and otherwise were unqualified to be involved in suspicious order monitoring determinations. It knew that it could not rely upon explanations given by national accounts managers ("NAMs") and other sales personnel with a financial interest in an account, absent an independent SOM investigation. It nevertheless allowed NAMs and sales representatives to "clear" flagged orders without any independent investigation by the SOM committee.

215. Mallinckrodt also utilized a customer service manager on its SOM team, even though that manager had a financial interest in clearing flagged orders. Mallinckrodt in fact reported internally the inherent conflict of interest and said that no one in that position should be involved on the SOM committee or in clearing flagged orders for that reason. Nevertheless, even after making that determination, Mallinckrodt still allowed that manager to remain on the SOM committee and to continue clearing orders on accounts for which he was responsible for several years. Not surprisingly, he did not ultimately classify any order as suspicious, and cleared each one on which he had input.

216. The sham system functioned as Mallinckrodt knew it would. Mallinckrodt's SOM team never once identified a suspicious order between 2008 and 2013. In two decades, Mallinckrodt reported at most ten orders as suspicious – total, across the entire country.

217. Mallinckrodt did not report any suspicious prescribers to Tennessee law enforcement. It never reported anyone to a Tennessee licensing board and never reviewed licensing board decision by pharmacies. It did not consult with any Tennessee public officials. Instead, it utilized a program that ignored any source of information that actually would have resulted in classifying flagged orders as suspicious, and allowed sales and customer personnel to dictate whether orders should be cleared when it knew that those sales personnel had an inherent conflict of interest and were manifestly unqualified to make that determination. In practice, Mallinckrodt just filled every order and routinely cleared the ones that were flagged, without reasonable justification and often with no investigation whatsoever.

4. Mallinckrodt Knew that It Was Facilitating Abuse and Diversion in Tennessee

218. Mallinckrodt National Account Managers ("NAM") knew that supplying opioids in prodigious amounts was creating drug addicts who would purchase more opioids.

Mallinckrodt's National Account Manager for Florida had a harrowing exchange with KeySource on this topic. When that NAM told KeySource that Mallinckrodt had "released" him to ship 1,200 bottles of opioids that KeySource, KeySource told Mallinckrodt to keep the "Keep 'em comin', Flyin' out of here. Its like people are addicted to these things or something. Oh, wait, people are" The Mallinckrodt NAM responded: "Just like Doritos; keep eating, we'll make more." In other words, Mallinckrodt knew that these orders were designed to create and feed drug addicts, and treated its opioids with same degree of care it would utilize for snack chips.

219. As discussed above, the Mallinckrodt drugs that Mallinckrodt sent to these pill mills supplied the Tennessee illegal drug market. Even after Mallinckrodt learned the drugs were being diverted to Tennessee through these pill mills, it continued to ship product to them.

220. For example, in a 12-month span July 2011 to June 2012:

- Mallinckrodt shipped (through Amerisource Bergen) hundreds of thousands of oxycodone pills (██████ Oxycodone 30 mg pills and ██████ oxycodone 15mg pills) to Jabos Pharmacy in Newport, Tennessee. There are fewer than 7,000 people in Newport. Mallinckrodt sent a questionnaire to AmerisourceBergen asking for information to justify Jabos's suspicious ordering. AmerisourceBergen delayed filling it out. It eventually provided a sham justification for Jabos that Mallinckrodt accepted without verifying. Mallinckrodt did not permanently shut off the flow of pills by denying chargebacks relative to Jabos, even after learning that a customer of Jabos tried to sell OxyContin to an AmerisourceBergen investigator (*i.e.*, to make an illegal drug deal). Upon information and belief, AmerisourceBergen continued to process and distribute orders for Jabos after learning this and/or other information that AmeriSourceBergen knew, based on its own criteria, indicated diversion. Mallinckrodt never placed Jabos on its chargeback restriction list and never reported it to the DEA.
- Mallinckrodt shipped (through Cardinal and Masters) hundreds of thousands of oxycodone pills (██████ Oxy 30 mg pills and ██████ Oxy 15 mg pills) to Riggs Drug in La Follette, TN. Through Cardinal, Masters, and AmerisourceBergen, it distributed over 100,000 oxycodone pills (another 20,600 Oxy 15 mg and another 82,300 Oxy 30 mg pills) to other pharmacies in LaFollette. There are fewer than 7,500 people in La Follette. Thus, in 12 months, Mallinckrodt alone sent hundreds of thousands of oxycodone pills (over ██████ pills) to a town with 7,500 people. Mallinckrodt never placed Riggs Drug on its chargeback restriction and never reported it to the DEA.

- Mallinckrodt shipped (through Cardinal, ABC, and McKesson) hundreds of thousands of oxycodone pills (██████ Oxy 15 mg and ██████ Oxy 30mg) to Rippeto in Morristown, TN, a town with approximately 29,000 people. Mallinckrodt had Rippeto on its “radar,” but allowed distributors to ship products to it anyway and made no effort to verify whether the orders were medically justified.
- Mallinckrodt shipped (through Cardinal, McKesson, and AmerisourceBergen) hundreds of thousands of oxycodone pills (██████ Oxy 15mg and ██████ Oxy 30mg pills) to pharmacies in Seymour, Tennessee (over ██████ pills), including a Food City pharmacy to which it sent over 180,000 Oxy 30 and Oxy 15 tablets combined. Seymour has a population of approximately 11,000 people. Mallinckrodt never placed this pharmacy on its chargeback restriction list and never reported it to the DEA.
- Mallinckrodt shipped ██████ Oxy 30s through AmerisourceBergen, McKesson, and Cardinal (including 39,600 to Rite Aid), and ██████ Oxy 30s through AmerisourceBergen, Cardinal, and Masters, for a total of over 100,000 oxycodone pills (██████ tablets). Jellico has 2,355 people.
- Mallinckrodt shipped ██████ Oxy 15s through AmerisourceBergen, McKesson, and Cardinal (including ██████ to CVS and ██████ to Rite Aid), along with ██████ Oxy 30s (including ██████ to CVS and ██████ to Rite Aid), for a total of hundreds of thousands of oxycodone pills (██████ pills), approximately twice the population of Murfreesboro.
- Mallinckrodt shipped ██████ Oxy 30s through McKesson (including ██████ to Rite Aid), ██████ Oxy 15s through McKesson and Cardinal Health (including ██████ to Rite Aid) for a total of tens of thousands of pills (██████ pills).

221. Similarly, in 2015, Mallinckrodt shipped to the Town of Celina tens of thousands of hydrocodone pills (██████ hydrocodone APAP 10mg tablets alone) through McKesson and Cardinal (including ██████ to Rite Aid). Celina has 1,379 people.

222. Mallinckrodt also ascertained that in 2011, four of Cardinal’s top 20 customers for Mallinckrodt products outside of Florida were located in Tennessee. These included a Lowe’s Drug in Maryville to which Cardinal shipped hundreds of thousands of oxycodone pills (██████ pills) in a year (Maryville has approximately 27,000 people), a Macs Pharmacy in Knoxville to

which Cardinal shipped hundreds of thousands of oxycodone pills ([REDACTED] pills) (more than the population of Knoxville as to just one pharmacy), hundreds of thousands of oxycodone pills ([REDACTED] pills) to Riggs Drug in La Follette (population 7,500), and over 100,000 oxycodone pills ([REDACTED] pills) to another Riggs Drug in Powell (under 22,000 people). Mallinckrodt continued to fill orders as to these accounts. It did not place Macs Pharmacy or either Riggs Drug location on its chargeback restriction list, nor did it report them to the DEA. As to Lowe's Drug, Mallinckrodt temporarily placed it on a chargeback restriction list, but later reinstated that pharmacy (i.e., took it off the chargeback restriction) to open up the flow of pills again. At any rate, Mallinckrodt's own Vice President of Sales for Specialty Generics has acknowledged that presence of these four Tennessee pharmacies on Cardinal's Top 20 list indicates that there was an illegal drug market for diverted pills in Tennessee.

223. In 2011, Mallinckrodt also initiated a program to enter into direct relationships with non-warehousing chains (including pharmacies and other retail outlets) to dispense Mallinckrodt opioids. Mallinckrodt used this program to "bridge the gap" between itself and those chain retailers. It did so in Tennessee even where the "gap" to be bridged would result in diversion. For example, Mallinckrodt sought to establish a direct relationship with Food City in Knoxville to boost sales of Mallinckrodt opioids, and Mallinckrodt continued to supply that location through the Drug Distributors in high volumes.

224. Even when a Mallinckrodt distributor itself got into legal trouble or lost its license for supplying pill mills, Mallinckrodt utilized *other distributors* to send its drugs to the *same problematic pharmacies and prescribers*. For example, In July 2011, Mallinckrodt stopped filling orders for Masters, which was supplying tens of thousands of pills per month to a Food City pharmacy in Knoxville. Mallinckrodt knew that Food City filled prescriptions for Dr. McNeil and

other Bearden pill mill prescribers (discussed above). Nevertheless, Mallinckrodt continued to ship substantial quantities of opioids to that Food City through another distributor, AmerisourceBergen, despite knowing that pills were likely being diverted.

225. Similarly, if one distributor provided Mallinckrodt information indicating that a certain pharmacy or prescriber was engaging in diversion, Mallinckrodt would place that pharmacy or prescriber on the no chargeback list *only as to that distributor* – but not as to other distributors supplying the same entity. In other words, if Mallinckrodt learned from a distributor that it would no longer supply Pharmacy X because that pharmacy was supplying pill mills or otherwise engaged in suspicious activity indicative of diversion, Mallinckrodt continued to allow chargeback as to that pharmacy by other distributors. Thus, through other distributors, Mallinckrodt knowingly would continue to fill orders intended to supply the *same suspicious pharmacy*. Mallinckrodt did so to maintain sales volume, despite knowing that the pills supplied to that pharmacy through another distributor were likely being diverted. These phenomena occurred in Tennessee and elsewhere.

226. Mallinckrodt knowingly entered and participated in the illegal drug market in Tennessee and the Counties. Mallinckrodt is aware of the extraordinary volume of opioid prescriptions in Tennessee in relation to other states referenced above, as well as the flood of opioids into East Tennessee at levels that cannot be medically justified. As reported by the CDC, Tennessee's oxycodone prescription rate is twenty-two times that of Minnesota's. Mallinckrodt knew (and knows) that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Mallinckrodt's products.

227. Despite controlling nearly 25% of the opioids market in Tennessee, Mallinckrodt has continued to supply opioids into Tennessee, East Tennessee, and the Counties unabated,

despite awareness that a substantial volume of those drugs are being abused and diverted into an illegal market. It also continues to fill suspicious orders, to utilize SOM systems that are designed to be ineffective, and to provide perverse incentives to its sales personnel to over-supply Tennessee and to assist in supplying pill mills.

228. Mallinckrodt knew that diversion of opioids has a human cost, including mortality and increased opioid addiction, and that states and localities bear the costs of responding to opioid overdoses.

vi. Endo's Misconduct also is Contributing to the Opioid Epidemic Ravaging the Opioid Epidemic Affected Counties

229. Endo also continues to participate in an illegal drug market that it helped create.

230. The original version of Opana ER, which was known by the street names “stop signs,” “the O bomb,” and “new blues,” is typically crushed by addicts and either snorted or injected.⁹⁰ “Crushing defeats the pill’s ‘extended release’ design, releasing the drug all at once.”⁹¹ This type of Opana abuse is particularly dangerous “because [Opana] is more potent, per milligram, than OxyContin, and users who are not familiar with how strong it is may be vulnerable to overdosing.”⁹²

231. Endo introduced Opana ER in 2006. For the next several years, it endeavored to capture market share and cut into the OxyContin market. As with the other defendants, Endo actively marketed to the highest volume prescribers of extended release opioids.

232. In July 2012, USA Today reported that Original Opana ER had overtaken

⁹⁰ Mary Wisniewski, *Painkiller Opana, new scourge of rural America*, Reuters (Mar. 26, 2012). Available at: <https://www.reuters.com/article/us-drugs-abuse-opana/painkiller-opana-new-scurge-of-rural-america-idUSBRE82Q04120120327>. [hereinafter

“Wisniewski, *Painkiller Opana, new scourge*”]

⁹¹ *Id.*

⁹² *Id.*

OxyContin as the drug of choice for prescription opioid addicts.⁹³

233. The USA Today article began by recounting how, in 2012 alone, there had been 11 pharmacy robberies in Fort Wayne, Indiana (a city of only 250,000 people), and “[i]n almost every case, the robbers asked specifically for Opana.”⁹⁴

234. The article went on to explain that “the Opana problem grew swiftly and sharply, particularly in several states where prescription drug abuse is deeply engrained.”⁹⁵ Among the states experiencing a dramatic increase in Opana ER abuse, the article listed the following:

- “Nassau County, N.Y. issued a health alert in 2011 when the New York City suburb saw the first signs of an alarming spike in Opana use. Medicaid data for the county showed prescriptions for extended-release Opana had increased 45% in six months.”⁹⁶
- “A DEA intelligence briefing noted increases in Opana [use] in Pennsylvania, including Philadelphia, and Delaware. In New Castle, Del., the DEA said, drug users had switched from uncrushable OxyContin to the crushable oxymorphone ‘for ease of use,’ pushing the price for a 40 mg tablet to \$65. A tablet costs \$4 to \$8 when purchased legitimately at a pharmacy.”⁹⁷
- “In Ohio, authorities in Akron, Cincinnati and Athens noted surges in Opana as a replacement for OxyContin, the state’s Substance Abuse Monitoring Network reported earlier [in 2012]. . . . Opana 40 mg tablets sell for \$60 to \$70 each, outpacing the once-popular old formulation OxyContin, which now sells for at least \$1 a milligram, the report said.”⁹⁸

235. The spike in Opana ER abuse and diversion was particularly pronounced in

⁹³ Donna Leinwand Leger, *Opana abuse in USA overtakes OxyContin*, USA Today (July 11, 2012). Available at: <http://usatoday30.usatoday.com/news/nation/story/2012-07-10/opana-painkiller-addiction/56137086/1>. [hereinafter “Leger, *Opana Abuse*”]

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

Tennessee's neighbor to the north, Kentucky.⁹⁹ In 2010, toxicology tests identified oxymorphone, the key ingredient in Opana ER, in 2% of Kentucky's overdose death cases, according to the Kentucky Office of Drug Control Policy.¹⁰⁰ By 2011, oxymorphone was present in the blood of 23% of overdose victims in the state.¹⁰¹

236. In 2011, the drugs most frequently found in overdose victims in Kentucky broke down as follows: Alprazolam (Xanax) – found in 286 overdose victims; Oxycodone (OxyContin) – found in 213 overdose victims; Hydrocodone (Vicodin) – found in 187 overdose victims; and oxymorphone (Opana ER) – found in 154 overdose victims.¹⁰²

237. Another 2012 news article, this one by Reuters, further highlighted the “Opana problem [that] has been reported by abuse experts around the country.”¹⁰³ As evidence of the “Opana problem,” the Reuters’ article pointed to Florida, where “the number of oxymorphone-related deaths rose to 493 in 2010, an increase of 109 percent from the previous year.”¹⁰⁴ Additionally, the article specifically referenced the fact that “users and dealers get painkillers from so-called ‘pill mills’ – storefront pain clinics that sell drugs for cash up front, often to out-of-state buyers who take them for resale.”¹⁰⁵

238. Of particular note, the 2012 Reuters article also quoted Detective Michael Donaldson – a Nashville, Tennessee detective who saw an increase in Opana abuse in the state – who said that “many small towns have ‘dirty doctors’ willing to give out unneeded

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ Wisniewski, *Painkiller Opana, new scourge*.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

prescriptions.”¹⁰⁶

239. As seen across the country, diversion of reformulated Opana ER was rampant in Tennessee following its introduction to the market. In October 2012, the CDC issued a health alert, saying a “cluster of at least 12 patients” (later raised to 15 victims) in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana.¹⁰⁷ These incidents immediately provided a clear and unmistakable signal to Endo that the “abuse-deterrent” formulation of Opana ER in fact was highly susceptible to intravenous abuse, which both Endo and the FDA considered to be a far more dangerous form of abuse than insufflation.

240. Furthermore, following the release of reformulated Opana ER, Hawkins County law enforcement officials told Endo that they were “overwhelmed by Opana abuse in their area.” They told Endo that local doctors were writing prescriptions to prescription drug abusers, that they had arrested and convicted multiple doctors for writing fraudulent prescriptions for drug traffickers, and that three people had died from a “suspect doctor” who opened a pain clinic in the area. Endo even interviewed one of the TTP victims, where it learned that abusing reformulated Opana ER by boiling and then injecting it was also occurring in nearby Johnson City and Kingsport. Despite receiving this clear safety signal, Endo nevertheless continued to call on Tennessee prescribers and distribute Opana ER not only in upper East Tennessee where the crisis erupted, but throughout the state.

241. During the same time frame, Endo commissioned an internal report which stated

¹⁰⁶ *Id.*

¹⁰⁷ Tom Dreisbach, *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, NPR – All Things Considered (Apr. 1, 2016). Available at: <https://www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak>.

that, in light of the non-availability of original OxyContin, Opana ER had become the key drug of choice for abusers and addicts. Endo also quickly recognized that higher injection rates (*i.e.*, intravenous abuse) were occurring in Tennessee. Indeed, in 2012, Endo acknowledged under oath that, following the introduction of reformulated OxyContin in August 2010, abuse of Opana ER spiked because drug users found that it was easier to snort or inject. This transfer of addicts and abusers from OxyContin to Opana ER was called the “squeezing the balloon” effect.¹⁰⁸ Endo nevertheless continued to detail Tennessee prescribers.

242. Indeed, when Purdue issued a reformulated, “abuse-deterrent” form of OxyContin in 2012, Endo recognized that pill seekers and other drug abusers were finding OxyContin more difficult to abuse, and that those drug abusers were turning to Opana ER because it was easy to crush and snort. Perceiving this “squeeze the balloon” effect, Endo consciously endeavored to capture the market share that Purdue was losing as addicts turned away from OxyContin.

243. In connection with its unsuccessful petition to have reformulated Opana ER designated as tamper-resistant, Endo publicly advocated that its *original* formulation of Opana ER was so dangerous and susceptible to abuse and diversion that it should be taken off the market.¹⁰⁹ Endo represented, *inter alia*, that its own testing shows that “96% of research subjects were willing to snort the Original Formulation (which could be crushed into powder).”¹¹⁰ It argued that allowing the Original Formulation onto the market “*will result in increases in drug abuse, misuse and*

¹⁰⁸ Collins PI Declaration ¶ 9.

¹⁰⁹ <https://www.beckershospitalreview.com/opioids/endo-to-receive-royalties-from-generic-opioid-it-once-called-unsafe-7-things-to-know.html>; *see also* *Endo Pharm. v. U.S. Food & Drug Admin., et al.*, Civil Action No. 1:12-cv-01936-RBW (Dkt. No. 5-1), Memo in Support of Motion for Preliminary Injunction, at 13 (stating that Endo represented to the FDA that permitting a generic manufacturer to introduce a generic equivalent to the original Opana ER “would allow abuse or diversion to continue . . .”).

¹¹⁰ *Id.* at p. 14.

diversion,” and that “[s]erious and predictable public harm would flow from entry and continued sale” of that product. Moreover, Endo acknowledged under oath that, following the introduction of reformulated OxyContin in August 2010, abusers turned to Opana ER as a drug that was easier to snort or inject.¹¹¹

244. Thereafter, Endo sued the FDA, seeking a preliminary injunction to prevent generic versions of the original Opana ER from coming onto the market. It represented to a federal court as follows:

Unless the Court intervenes and issues an injunction to preserve the status quo, on January 1, 2013, a generic version of the Original Formulation drug will be released. If this occurs . . . the public interest will be substantially and irreparably injured by release of generic versions of a drug which relies upon a drug that was withdrawn for safety reasons and that is subject to abuse and misuse that FDA acknowledges and against which it has long fought.

...

Unless the Court intervenes and issues a preliminary injunction, there is a significant risk that a readily crushable, and thus admittedly less safe, opioid drug will serve as the RLD for generic drugs that will then be subject to abuse and misuse. FDA inaction will have facilitated precisely the type of harm to the public interest against which it has fought for many years.¹¹²

Endo also argued that introducing the generic equivalent “*will result in drug abuse, misuse and diversion with a predictable upsurge in serious injuries and overdose deaths.*”¹¹³

245. Thus, in 2012, Endo publicly acknowledged that it knew that original Opana ER was highly susceptible to abuse and diversion, that it was such a threat to public health and safety that neither it nor any equivalent should be allowed on the market, that diversion and adverse public health effects (including “serious injuries and overdose deaths”) are “predictable”

¹¹¹ Collins Declaration ¶ 9.

¹¹² *Id.* at p. 3.

¹¹³ *Id.*

consequences of producing and distributing opioids that are subject to abuse. However, even as Endo was arguing that original Opana ER would harm people, it continued to distribute original Opana ER throughout the country *for the next 9 months*, including in Tennessee. Once the stores were exhausted, Endo then voluntarily removed that original formulation of Opana ER on the basis of those stated safety concerns.

246. In a conference call with investors on February 28, 2013, Endo officials were asked about the reports of injection abuse, specifically those in Tennessee.¹¹⁴ On that call, Ivan P. Gergel, Endo's chief scientific officer at the time, said: "We've designed the Opana crush-resistant formulation to be crush-resistant, to avoid primarily the nasal root of abuse. . . . Clearly, we are looking at this data . . . but it's in a very, very distinct area of the country."¹¹⁵ Endo clearly knew that addiction and abuse of Opana ER was centered in Tennessee. It could have stopped calling on doctors in Tennessee and stopped filling orders for Opana ER intended for distribution in Tennessee to stop the abuse and diversion. Instead, it chose to continue to call on Tennessee prescribers, particularly its highest volume prescribers. And it continued to push pills on prescribers and market Opana ER in Tennessee the same way as the rest of the country: Tennessee representatives received the same instructions relative to Tennessee prescribers as everywhere else.

247. Endo's sales department received IMS Health data that identified the volume of Opana prescriptions written by particular providers in Tennessee. Endo reviewed these reports regularly. It used that data to target physicians to prescribe more Opana ER.

248. Later, in 2014, a case study from the University of Tennessee School of Medicine

¹¹⁴ *Id.*

¹¹⁵ *Id.*

described the university-based hospital's experience of a series of ten patients with characteristic clinical and laboratory findings of Thrombotic Microangiopathy (TMA) and documented recent history of illicit intravenous Opana ER use.

249. Endo itself recognized abuse and diversion of Opana ER in Tennessee was especially acute in Tennessee. Endo collected information from multiple sources reflecting the incidence of abuse of Opana ER in Tennessee relative to other drugs and the source of those drugs. Based on that data, in March 2017, Endo's Chief Medical Officer, Neil Shusterman acknowledged to the FDA in March 2017 that ***75% of all abuse of reformulated Opana ER occurred in Tennessee*** over the post-monitoring period for reformulated Opana ER, even though Tennessee has just 2% of the nation's population. Shusterman also acknowledged that "while Endo was receiving quarterly surveillance reports in real-time, NAVIPPRO informed us ***that a continually increasing proportion of Opana ER cases was coming from Tennessee.***"¹¹⁶ In fact, Tennessee's abuse rates were so high that Endo chose to exclude them from its nationwide calculations. Dr. Shusterman presented an alarming picture of acute problems with Opana ER and other opioids in Tennessee:

- a. Relative to the rest of the country, rates of Opana ER injections in Tennessee were exceptionally high for oxycodone immediate release, morphine extended release, and OxyContin before 2012. Endo stated that there was "clearly an intravenous abuse issue in Tennessee that goes beyond Opana ER[.]"
- b. Injection of abuse of Opana ER ***increased*** by approximately a factor of three after the reformulation in 2012.
- c. Following the reformulation, injection abuse of Opana ER in Tennessee increased.
- d. Tennessee had an "uncommonly high abuse" not only for Opana ER, but also for

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<https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM553190.pdf>, Transcript of March 13, 2017 FDA Hearing, at 71.

many other opioids.

- e. The data indicated that Tennessee drug abusers who needed substance treatment “might be a more severe group of opioid abusers with more intravenous experience than those in other states.”¹¹⁷
- f. Endo therefore noted a special “effect of Tennessee,” which “warrants that the two regions be looked at separately.”¹¹⁸
- g. Endo acknowledged that rates of IV abuse in northeast Tennessee “have been documented for a long time.”¹¹⁹
- h. Tennessee had “abuse prevalence an order of magnitude higher than in other parts of the United States, and increased intravenous abuse of all opioids, particularly Opana ER.”¹²⁰
- i. Tennessee had a special “abuse psychology.”¹²¹
- j. When asked by the FDA whether Endo could “determine how many tablets of oxymorphone that you ship to a specific area in a given year,” Endo responded: “Absolutely.”¹²²

250. Like the other defendants, Endo employed a sales force that specifically targeted high-volume opioid prescribers to convince them to prescribe more Opana ER or to prescribe it instead of OxyContin, as well as to prescribe Endocet and other branded Endo drugs. Endo identified these high-volume prescribers as the softest targets. Like other defendants, it compiled data showing which prescribers issued the most opioid prescriptions and detailed those prescribers repeatedly, including prescribers in Tennessee and in the Counties. As with the other producer defendants, Endo recognized that detailing doctors drives prescriptions, and it provided volume-based bonuses or commissions to sales representatives. Endo’s detailing efforts were successful.

¹¹⁷ *Id.* at 77.

¹¹⁸ *Id.* at 77.

¹¹⁹ *Id.* at 91.

¹²⁰ *Id.* at 100.

¹²¹ *Id.* at 132.

¹²² *Id.* at 133.

Opana ER sales rose, and the vast majority of prescriptions for Opana ER came from doctors that Endo detailed. Upon information and belief, the same holds true as to Endo's other branded opioids.

251. Endo knew that supplying large quantities of opioids to a region necessarily correlates with increased rates of abuse and diversion. In other words, it knew that the more opioids are available in a given area, the more they will be abused. For example, in 2014, its Risk Management analyzed Inflexxion data and determined that "[t]he number of prescriptions dispensed within a geographic region is related to a product's potential diversion and abuse."¹²³ Endo also determined that the level of prescriptions dispensed for reformulated Opana ER in Tennessee was among the highest among states within the dataset that Endo was analyzing.

252. Endo also recognized that the vast majority of opioids that are abused originate with prescriptions from a healthcare provider, as opposed to another source (pharmacy theft, etc.). Endo recognized that there was an illegal market for its products and knew that supplying Opana ER and other prescription opioids would cause diversion to addicts. Endo knew that Opana ER became the opioid of choice for abusers in Tennessee. Nevertheless, it continued to push pills on the most dangerous, highest-volume prescribers and to encourage them to prescribe more Opana ER, knowing by doing so it would result in its drugs reaching the illegal drug market in increasing volumes.

253. In fact, Endo recognized that even legal, non-fraudulent opioid prescriptions constitute diversion when a naïve doctor willingly writes prescriptions for powerful opioids to pill seekers and prescription drug abusers who sell the prescriptions wholesale. In other words, even as to prescribers did not know any better, Endo recognized that writing scripts for pill seekers and

¹²³ Endo-Opioid MDL-01333144.

abusers was a form of diversion. Endo knew that this form of diversion was occurring in Tennessee and the Counties at alarming rates, and that any effort to convince those doctors to prescribe more opioids would cause increased diversion. It nevertheless continued to push pills on these prescribers, convincing them to prescribe more Opana ER despite knowing that this would result in further abuse and diversion in Tennessee – which had an acute abuse and diversion problem that Endo itself recognized.

254. Both before and after the reformulation of Opana ER, Endo pushed Opana ER to Tennessee prescribers who were operating pill mills, some of whom eventually were indicted. Endo actively pushed Opana ER on these prescribers even after receiving reports of suspected criminal activity.

- a. For instance, in 2007, Endo received word from a district manager questioning whether Dr. Frank McNeil's practice was legitimate. The district manager indicated that Dr. McNeil was prescribing 80-100 scripts per week for extend release opioids, that 90% of his scripts were for OxyContin (*i.e.*, one product), that he was not actually seeing patients regularly, had physicians' assistants who rotated through the office every 6 months, that he was receiving cash for OxyContin from "a lot" of his patients, and was prescribing OxyContin at a level that "seems almost impossible even for a pain clinic." Endo nevertheless told the district manager that Endo could continue to call on that prescriber, noting internally that Dr. McNeil was responsible for 20% of the sales volume within one of Endo's sales territories. As described herein, in 2018 Tennessee ultimately stripped Dr. McNeil's medical license.
- b. Endo also facilitated diversion by Dr. Mohamed in Morristown. After successfully courting Dr. Mohamed and convincing him to prescribe more Opana ER, Dr. Mohamed informed him that his "patients" could not fill their Opana ER prescriptions because the pharmacies had run out. Essentially, he had written so many scripts that local pharmacies ran out of sufficiently supply to meet them. Endo then contacted numerous other local pharmacies and Endo's distributors in an effort to stock those pharmacies to fill Dr. Mohamed's prescription and make up for the shortage. Dr. Mohamed was Endo's highest prescriber in Tennessee. Endo never formally identified Dr. Mohamed as a suspicious subscriber.

These are just representative examples. Endo called on suspicious prescribers in the Counties as well, including prescribers who were ultimately disciplined.

255. Endo sales representatives also called on pharmacies to ensure that the pharmacies stocked Endo products.

256. In 2011, the FDA directed Endo to conduct a post-marketing epidemiological study concerning the abuse deterrence potential of reformulated Opana ER. Endo conducted a study and learned through NAVIPPRO reports that Opana ER reformulated during the study period was procured for abuse primarily nationwide through *drug dealers*, at a rate 12 to 15 times higher than the national average for prescription drug abuse. As Endo later acknowledged to the FDA in March 2017, the same reports showed that abuse of Opana ER in Tennessee was multiple orders of magnitude higher than the rest of the country.

257. Endo tried to convince the FDA that patterns of abuse would be different and lower with the reformulated version. However, it turned out that reformulated Opana ER resulted in higher rates of intravenous abuse because of the specific chemical properties of the drug. This led to outbreaks of Thrombotic Microangiopathy, Hepatitis C, and HIV. Within three months of the reformulation hitting the market in 2012, Endo learned about the spike in intravenous and the associated outbreaks. Despite such troubling reports of its newly-reformulated Opana ER product being abused intravenously, internally Endo's sales team was being told with respect to their detailing that it was "business as normal." Indeed, *four years* after first receiving reports of TTP from abuse of the newly-formulated Opana ER in Tennessee, Endo executives were discussing the fact that they had not yet solved "the intravenous issue."

258. Endo had evidence that 10% of prescriptions nationwide were coming from East Tennessee, even though that region has less than 0.7% of the nationwide population. This disproportionately included small communities, such as the Counties herein, where there were far more prescriptions than people, a pervasive illegal drug network for prescription opioids (which

included both pharmacies and prescribers who were engaged in criminal conduct and unlawful practices concerning prescription opioids), and high rates of addiction, NAS deaths, and overdose deaths.

259. During the same time frame that Endo reformulated Opana ER was being acutely abused and diverted in Tennessee, Endo engaged in a lobbying campaign to have Tennessee exclude a competing generic version of the drug (which was not “tamper resistant”) from the market, and characterized Tennessee as a “critical” state for sales and marketing purposes that Endo needed to “win” in order for Opana ER to be successful. Essentially, at the same time that Endo identified that reformulated Opana ER was being abused intravenously in Tennessee at exceptionally high rates relative to the rest of the country, Endo simultaneously was *targeting* Tennessee as a “critical” and “key” state where it needed to drive more sales. In service of that goal, it engaged in a multi-pronged effort to drive sales of reformulated Opana ER, including targeting high-volume prescribers, including physicians, nurse practitioners, and physicians assistants, and “selling” the benefits of reformulated Opana.

260. Indeed, by 2014, the problem with Opana ER abuse and diversion in Tennessee had gotten so bad that Endo’s President internally considered whether to close off distribution of Opana ER entirely. Endo recognized that its drugs were being abused and diverted at such volumes that stopping distribution entirely was warranted. However, Endo never took that step. Instead, it continued to flood Tennessee with Opana ER so as not to lose sales revenue. Indeed, during the same time frame, Endo was actively pushing Opana ER on the highest volume Tennessee prescribers who were pushing pills into the illegal drug market in alarming quantities. As of early 2014, 7 of Endo’s top 20 prescribers were located in Tennessee, including prescribers in Knoxville (Dr. Mohamed among them), Nashville, and Memphis. Endo also identified the top OxyContin

prescribers (including Dr. Mohamed) and directed its sales force to target them to prescribe a larger share of Opana ER.

261. Endo knew that it had a responsibility to monitor and report suspicious orders. Nevertheless, it implemented a system for detecting and reporting that was designed to fail. Endo utilized a structure that encouraged sales representatives to call on pill mill prescribers or over-prescribers and that, by the same token, disincentivized those representatives from reporting suspicious practices. Sales representatives had an inherent conflict of interest because reporting their customers would reduce their compensation. By the same token, Endo did not penalize any sales representatives for having supplied a suspicious prescriber. Furthermore, Endo's Chief Medical Liaison believed that sales personnel were not qualified to detect and report signs of abuse and diversion, and should not have been involved in that important function. Nevertheless, Endo entrusted the sales force to be only source of abuse detection and reporting for Endo. Not surprisingly, sales representatives did not report a single instance of abuse or diversion by a Tennessee prescriber. Nor, for that matter, did Endo classify an order from a distributor as suspicious.

262. Relative to Tennessee, it filled *every single order ever submitted to it* and continued to push Opana ER and other dangerously addictive pills on the highest-volume prescribers essentially no matter what information it learned.

263. Endo knowingly facilitated downstream diversion of its products and participated in Tennessee's illegal drug market for opioids. Its effort resulted in rampant abuse and diversion of Opana ER nationwide, in Tennessee, and in the Counties.

264. **The ongoing, and excessive, abuse of Opana ER reached such a critical level that, on June 8, 2017, the FDA took the unprecedented step of demanding that Endo**

permanently remove the drug from the marketplace.¹²⁴ According to a FDA press release, the agency's "decision [was] based on a review of all available post marketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation."¹²⁵ The FDA further stated that its decision to remove the opioid from the marketplace followed a March 2017 FDA advisory committee meeting where a group of independent experts voted that "the benefits of reformulated Opana ER no longer outweigh its risks."¹²⁶

265. On July 6, 2017, Endo announced that it would voluntarily remove Opana ER from the market, citing the FDA's concerns of diversion.¹²⁷

266. Despite evidence of widespread abuse, Endo continued to push its drug into the addiction pipeline in Tennessee, including the Counties, with its highly addictive, and deadly, prescription opioid, all the while knowing that it was being diverted into the illicit market. From September 2015 through August 2017, Endo's Opana ER and Endocet were the second and third most-prescribed branded opioids throughout Tennessee, respectively, following only OxyContin.¹²⁸

267. Furthermore, after the new Opana ER formulation was removed from the market at the FDA's request in July 2017, Endo pivoted and entered into a contract with Impax to *share profits* from sales of a generic equivalent to the *original Opana ER* sold under the "Impax" name.

¹²⁴ FDA Press Release. *FDA requests removal of Opana ER for risks related to abuse*. June 8, 2017. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ CBS News online. *Opana ER opioid painkiller pulled from the market by FDA request*. July 7, 2017. Available at: <https://www.cbsnews.com/news/drug-opana-er-opioid-painkiller-pulled-from-the-market-by-fda/> (last visited Dec. 28, 2017).

¹²⁸ QuintilesIMS Data.

The agreement allows for profit-sharing for the next 11 years, starting January 1, 2018. As numerous observers have pointed out, “Endo is profiting off of the very drug it said was unsafe to stay on the market.”¹²⁹ By Endo’s own admission, continuing to distribute this product “will result in increases in drug abuse, misuse and diversion,” along with “serious and predictable public harm.” Accordingly, Endo has known all along that streaming its opioid products into communities “predictably” results in high levels of addiction, overdose death, and illegal diversion – but it does not care, so long as it continues to turn a profit.

268. Endo knowingly entered and participated in the illegal drug market in Tennessee and the Counties. Endo is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Endo knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Endo’s products. Endo also knowingly participated in the illegal drug market in the Counties by supplying quantities of its products to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

269. Also, Endo knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing of opioids in Tennessee and the Opioid Epidemic Affected Counties, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing of prescription opioids; and (iii) permitting and directing sales representatives to visit prescribers whose were engaging in suspicious conduct.

vii. Teva’s Misconduct is Contributing to the Opioid Epidemic Ravaging the

¹²⁹ <https://www.beckershospitalreview.com/opioids/endo-to-receive-royalties-from-generic-opioid-it-once-called-unsafe-7-things-to-know.html>.

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270. Teva continues to flood East Tennessee with opioids in an amount that clearly contributes to the illegal opioid drug market.

271. Teva's generic oxycodone and hydrocodone products both represent the largest market share for either product throughout Tennessee according to IMS Health Data. These quantities of opioid pills clearly exceed the number that would be appropriate for normally prescribed therapeutic use and contribute to the illegal Tennessee opioid market.

272. Teva also knowingly participated in the illegal drug market in Tennessee by supplying suspicious quantities of its products to suspect physicians and pharmacies in Tennessee, without disclosing suspicious orders as required by applicable regulations.

273. According to IMS data, from September 2015 to August 2016, Teva accounted for 33.5% of the hydrocodone prescribed in Tennessee, 28.8% of the oxycodone prescribed in Tennessee, 16.8% of the oxymorphone, and 1.6% of the hydromorphone. This amounted to 1,913,712 Tennessee opioid prescriptions filled by Teva in one year. On average, this means Teva filled an opioid prescription for one out of every 3.5 Tennesseans during that year.

274. During the same timeframe of September 2016 through August 2017, Teva accounted for 32.3% of Tennessee hydrocodone prescriptions, 25.1% of its oxycodone prescriptions, 1.8% of its oxymorphone prescriptions, and 1.8% of its hydromorphone prescriptions. This amounted to 1,619,143 Tennessee opioid prescriptions filled by Teva in one year. On average, this means Teva filled an opioid prescription for one out of every 4.1 Tennesseans during that year.

275. Teva's role relative to branded drugs involved knowing participation in the illegal drug market. Cephalon, a pharmaceutical company purchased by Teva in 2011, sold two opioid